**Інформація, отримана з іноземних систем повідомлення про продукцію, що становить серйозний ризик, за період 01.04.2024 – 30.06.2024**

**Швейцарія**

## <https://fsca.swissmedic.ch/mep/>

| **Date** | **Manufacturer** | | **Trade name** | **Product description** | | **Information** | | **Swissmedic reference** | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 28.06.2024 | Löwenstein Medical SE & Co. KG | Leoni Plus Model: 0217004 / 0217400 S/N: 0217004hul13400504, 0217004hul61501809, 0217004hul99970891 SW-Version: Version 3.2.12 up to 3.2.21 | | | MD: Neonatal intensive-care ventilator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240628_18/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240628_18/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240628_18/documents/2) | | Vk\_20240628\_18 |
| 28.06.2024 | Covidien llc | Puritan Bennett PB560 Model: 4096600-01 S/N: all  Puritan Bennett 560 Model: 4096600 S/N: all | | | MD: Portable electric ventilator  MD: Portable electric ventilator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240628_07/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240628_07/documents/1) | | Vk\_20240628\_07 |
| 28.06.2024 | LSO Medical | Ringlight fiber Model: ORLF000003 Lot: All batches | | | MD: Laser beam guide, standard, single-use | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240621_22/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240621_22/documents/1) | | Vk\_20240621\_22 |
| 27.06.2024 | Shenzhen Besdata Technology Co., Ltd | Automated External Defibrillator Model: BeneHeart C1A; BeneHeart C2 | | | MD: Non-rechargeable public automated external defibrillator | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240626_21/documents/0) | | Vk\_20240626\_21 |
| 27.06.2024 | DH Healthcare GmbH | DeepUnity Viewer SW-Version: all Versions | | | MD: Picture Archiving And Communication Systems | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240619_18/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240619_18/documents/1) | | Vk\_20240619\_18 |
| 27.06.2024 | Abaxis Inc | General Chemistry 13 Model: 400-1029 (single pouch) Lot: 4065AB8 | | | IVD: Chemistry Analysers - Consumables | | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_18/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_18/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_18/documents/2) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_18/documents/3) | | Vk\_20240618\_18 |
| 26.06.2024 | COPAN ITALIA SpA | Transystem / Specimen collection device Model: 900-0370 Lot: 230397900, 230535300, 230627500, 231877400 | | | MD: Sample Collection Swabs With Transport Medium | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240625_02/documents/0) | | Vk\_20240625\_02 |
| 26.06.2024 | QuidelOrtho (Ortho-Clinical Diagnostics Inc.) | Chemistry Products FS Diluent Pack 3 Model: 6801754 Lot: 01-1645 | | | IVD: Buffered sample diluent IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240620_27/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240620_27/documents/1) | | Vk\_20240620\_27 |
| 26.06.2024 | Siemens Healthcare Diagnostics Products Ltd. | IMMULITE/IMMULITE 1000 TNF -alfa Model: LKNF1/10381417 Lot: All in-date lots S/N: N/A | | | IVD: TNF-alpha/TNF-beta IVD, kit, fluorescent immunoassay | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240620_19/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240620_19/documents/1) | | Vk\_20240620\_19 |
| 26.06.2024 | Abbott Laboratories | Alinity hq Analyzer Model: 09P68-01 S/N: See FSN SW-Version: 5.6 and below | | | IVD: Haematological cell analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_12/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_12/documents/1) | | Vk\_20240618\_12 |
| 12.06.2024  (Updated 26.06.2024) | Stryker Neurovascular | Synchro Guide wire Model: see FSN Lot: See attached FSN | | | MD: Cardiac/peripheral vascular guidewire, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_04/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_04/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_04/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_04/documents/3) | | Vk\_20240610\_04 |
| 07.11.2023  (Updated 26.06.2024) | Medtronic Inc. | LINQ II Insertable Cardiac Monitor Model: LNQ22 S/N: see FSN | | | AIMD: Implantable Diagnostic Arrhythmias Recording Cardiac Devices | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/1) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/2) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/3) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/4) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/5) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/6) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/7) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/8) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/9) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/10) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/11) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/12) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/13) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/14) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/15) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/16) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/17) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/18) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/19) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231102_21/documents/20) | | Vk\_20231102\_21 |
| 25.06.2024 | Beckman Coulter , Inc. | Access 2 Immunoassay Analyzer Model: 81600N S/N: see FSN SW-Version: Not applicable | | | IVD: Chemiluminescent immunoassay analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240624_08/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240624_08/documents/1) | | Vk\_20240624\_08 |
| 11.06.2024  (Updated 25.06.2024) | Thermo Fisher Scientific Oy | Cholesterol Model: 981813 Lot: WB28, WA26 | | | IVD: Total cholesterol lipid IVD, kit, spectrophotometry | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/0) [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/2) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/3) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/4) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/5) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/6) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/7) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_17/documents/8) | | Vk\_20240606\_17 |
| 17.05.2024  (Updated 25.06.2024) | Exactech Inc. | Exactech Optetrak Knee Patella UHMWPE Model: see FSN Lot: all | | | MD: Polyethylene patella prosthesis | | [DE-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/0) [DE-1-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/1) [FR-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/2) [FR-1-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/3) [FR-2-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/4) [FR-2-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/5) [IT-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/6) [IT-1-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/7) [EN-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/8) [EN-1-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/9) [EN-2-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/10) [EN-2-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_11/documents/11) | | Vk\_20240422\_11 |
| 21.06.2024 | Proteomedix AG | Proclarix Risk Calculator Model: PCLX RICALI SW-Version: V2.1.1 and V2.2.1 | | | IVD: Mixed Panel Multiparameter Analysers - Ivd Medical Device Software | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_02/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240618_02/documents/1) | | Vk\_20240618\_02 |
| 19.06.2024  (Updated 21.06.2024) | Philips Medical Systems | IntelliVue X3 Model: 867030 S/N: See FSN SW-Version: P.0 with dedicated configuration profile | | | MD: Multiple vital physiological parameter monitoring system, clinical | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240614_06/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240614_06/documents/1) | | Vk\_20240614\_06 |
| 18.06.2024  (Updated 21.06.2024) | bioMérieux SA | VIDAS FPSA 30TESTS - 30440 Model: 30440 Lot: see FSN S/N: N/A SW-Version: N/A | | | IVD: Free (unbound) prostate specific antigen (fPSA) IVD, kit, enzyme immunoassay (EIA) | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_29/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_29/documents/1) | | Vk\_20240611\_29 |
| 11.03.2024  (Updated 21.06.2024) | Philips Respironics, Inc | Trilogy Evo Model: all Models  Trilogy Evo O2 Model: all Models  Trilogy EV300 Model: all Models | | | MD: Portable electric ventilator  MD: Portable electric ventilator  MD: Portable electric ventilator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240310_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240310_03/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240310_03/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240310_03/documents/3) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240310_03/documents/4) | | Vk\_20240310\_03 |
| 19.06.2024 | GE Healthcare Japan Corporation | Optima MR360, Brivo MR355 SW-Version: see FSN  Discovery MR750w 3.0T, Discovery MR750 3.0T, Optima MR450w 1.5T, Discovery MR450 1.5T, SIGNA Architect, SIGNA Artist  1.5T Signa HDxt, SIGNA Creator, SIGNA Explorer  SIGNA Voyager | | | MD: MRI system, full-body  MD: Full-body MRI system, superconducting magnet  MD: Full-body MRI system, superconducting magnet  MD: Full-body MRI system, superconducting magnet | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_03/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_03/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_03/documents/3) | | Vk\_20240617\_03 |
| 19.06.2024 | Vyaire Medical, Inc. | AirLife Model: 2K8000, 2K8001, 2K8004F, 2K8004C2, 2K8005, 2K8005F, 2K8005C2, 2K8017, 2K8004; 2K8000, 2K8001, 2K8004F, 2K8004C2, 2K8005, 2K8005F, 2K8005C2, 2K8017, 2K8004 | | | MD: Rebreathing oxygen face mask | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_02/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_02/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_02/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240617_02/documents/3) | | Vk\_20240617\_02 |
| 19.06.2024 | Shenzhen Mindray Bio-medical Electronics Co., Ltd. | BeneHeart D1 Automated External Defibrillator Model: see FSN S/N: FQ-7A012385; FQ-89020768 | | | MD: Physiologic-monitoring defibrillation system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240614_25/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240614_25/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240614_25/documents/2) | | Vk\_20240614\_25 |
| 19.06.2024 | DH Healthcare GmbH | ORBIS Medication 3.x | | | MD: General Medicine Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240613_14/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240613_14/documents/1) | | Vk\_20240613\_14 |
| 19.06.2024 | Olympus Medical Systems Corp. | HD Lightweight Pendulum Camera Head Model: CH-S200-08-LB, N6131760 S/N: see FSN | | | MD: Endoscope video camera | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_20/documents/0) | | Vk\_20240611\_20 |
| 02.04.2024  (Updated 19.06.2024) | RaySearch Laboratories AB | RayStation Model: RayStation RayPlan S/N: See FSN SW-Version: See FSN | | | MD: Various Radiotherapy And Radiosurgery Instruments - Software Accessories | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/2) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/3) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/4) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/5) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/6) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_06/documents/7) | | Vk\_20240402\_06 |
| 18.06.2024 | Mint Medical GmbH | Mint Lesion SW-Version: 3.9.3 , 3.9.4 | | | MD: Radiology Instruments - Software Accessories | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240612_22/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240612_22/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240612_22/documents/2) | | Vk\_20240612\_22 |
| 18.06.2024 | Beckman Coulter , Inc. | DxI 9000 Access Immunoassay Analyzer Model: C11137 S/N: see FSN SW-Version: na | | | IVD: Chemiluminescent immunoassay analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_15/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_15/documents/1) | | Vk\_20240611\_15 |
| 28.05.2024  (Updated 18.06.2024) | Waldemar Link GmbH & Co. KG | Endo-Model-M Model: see FSN Lot: All after manufacturing date 2022-06 until manufacturing date 2024-06 SW-Version: N/A  Endo-Model SL Model: see FSN Lot: All after manufacturing date 2022-06 until manufacturing date 2024-06 | | | MD: Uncoated knee tibia/insert prosthesis  MD: Rotating hinged total knee prosthesis | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_14/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_14/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_14/documents/2) | | Vk\_20240522\_14 |
| 30.04.2024  (Updated 18.06.2024) | Stryker Orthopaedics | EXETER 2.5 I M PLUG Model: 0939-0-108; 0939-0-110; 0939-0-112; 0939-0-114 Lot: N0398, N0352, N0397, N0388, N0329, N0339, N0340, N0400, N0404, N0347, N0345, N0346 S/N: N/A | | | MD: Polymer orthopaedic cement restrictor, non-bioabsorbable | | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_10/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_10/documents/1) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_10/documents/2) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_10/documents/3) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_10/documents/4) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_10/documents/5) | | Vk\_20240429\_10 |
| 17.06.2024 | Terumo BCT Europe N.V. | Spectra Optia Apheresis System Model: ALL | | | MD: Apheresis system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_14/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_14/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_14/documents/2) | | Vk\_20240606\_14 |
| 22.04.2024  (Updated 17.06.2024) | Otsuka Electronics Co., Ltd | Adamonitor SC S/N: see FSN SW-Version: User3.05/FS3.07/Slave3.06 | | | MD: Apheresis system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_06/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_06/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_06/documents/2) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_06/documents/3) | | Vk\_20240405\_06 |
| 16.05.2023  (Updated 17.06.2024) | Phadia AB | EliA GBM Well Model: 14-5514-01, 14-5514-10, 14-5514-41 Lot: All | | | IVD: Glomerular basement membrane antibody (Goodpasture antibody) IVD, kit, fluorescent immunoassay | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230512_16/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230512_16/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230512_16/documents/2) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230512_16/documents/3) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230512_16/documents/4) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230512_16/documents/5) | | Vk\_20230512\_16 |
| 14.06.2024 | Zoll Medical Corporation | Powerheart AED G5 Model: G5S-XXX | | | MD: Non-rechargeable public automated external defibrillator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_06/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_06/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_06/documents/2) | | Vk\_20240610\_06 |
| 14.06.2024 | Micrel Medical Devices S.A. | Rythmic Ultima Model: See FSN SW-Version: 1.0 A, 1.0 B, 1.0 C | | | MD: Bedside infusion pump, single-channel | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240607_01/documents/0) | | Vk\_20240607\_01 |
| 22.05.2024  (Updated 14.06.2024) | implantcast GmbH | MUTARS RS Extension Sleeve Model: 67300025, 67300125  MUTARS RS Stem Model: 67611220, 67611220N, 67622514, 67621512, 67622012, 67622515 | | | MD: Sleeve femoral extension  MD: Uncoated femoral stem prosthesis, modular | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_25/documents/0) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_25/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_25/documents/2) | | Vk\_20240514\_25 |
| 21.05.2024  (Updated 13.06.2024) | Ethicon Endo-Surgery, LLC | Vicryl and Vicryl Plus  PDS (polydioxanone) suture Model: N/A; Attachment 3 - Product details Lot: Attachment 3 - Product details  PDS Plus Antibacterial Suture Model: N/A; Attachment 3 - Product details Lot: Attachment 3 - Product details  MONOCRYL and MONOCRYL PLUS sutures Model: N/A; Attachment 3 - Product details Lot: Attachment 3 - Product details | | | MD: Polyester suture, bioabsorbable, multifilament, non-antimicrobial  MD: Polyester suture, bioabsorbable, monofilament, non-antimicrobial  MD: Polyester suture, bioabsorbable, monofilament, antimicrobial  MD: Polyester suture, bioabsorbable, monofilament, antimicrobial | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_17/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_17/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_17/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_17/documents/3) | | Vk\_20240514\_17 |
| 01.09.2021  (Updated 13.06.2024) | Roche Diagnostics GmbH | cobas EGFR Mutation Test, v2 IVD Model: 07248563190 | | | IVD: Epidermal growth factor receptor (EGFR) gene mutation/mRNA expression IVD, kit, nucleic acid technique (NAT) | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210827_15/documents/0) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210827_15/documents/1) | | Vk\_20210827\_15 |
| 12.06.2024 | Haemotronic S.P.A | Aqualine, Haemofiltration line Model: see FSN | | | MD: Haemodialysis blood tubing set, single-use | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_19/documents/0) | | Vk\_20240610\_19 |
| 12.06.2024 | Ypsomed AG | mylife YpsoPump Orbit micro 2.0 infusion sets Model: MYOYP2-1851, MYOYP2-2451, MYOYP2-3151, MYOYP2-2481, MYOYP2-3181, MYO2-1005, MYO2-1008 | | | MD: Electric infusion pump administration set, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_25/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_25/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_25/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_25/documents/3) | | Vk\_20240606\_25 |
| 12.06.2024 | Abbott Medical | Proclaim Model: 3660, 3661, 3662, 3664, 3665, 3667 S/N: All serial numbers SW-Version: N/A | | | AIMD: Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, implantable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_18/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_18/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_18/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_18/documents/3) | | Vk\_20240606\_18 |
| 12.06.2024 | Schiller Medical | SCHILLER Model: DEFIGARD HD-7 S/N: All SW-Version: Soft 1 | | | MD: Physiologic-monitoring defibrillation system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240605_18/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240605_18/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240605_18/documents/2) | | Vk\_20240605\_18 |
| 04.06.2024  (Updated 12.06.2024) | Qiagen GmbH | QIAcube Connect MDx Model: 9003070 | | | IVD: Specimen processing instrument IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_01/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_01/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_01/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_01/documents/3) | | Vk\_20240530\_01 |
| 13.05.2024  (Updated 12.06.2024) | Philips Respironics, Inc | BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro Model: Please refer to Device Affected List Lot: Please refer to Device Affected List | | | MD: Portable electric ventilator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240416_05/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240416_05/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240416_05/documents/2) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240416_05/documents/3) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240416_05/documents/4) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240416_05/documents/5) | | Vk\_20240416\_05 |
| 11.06.2024 | BioFire Diagnostics, LLC | BioFire BCID2 Panel Model: RFIT-ASY-0147 Lot: All BIOFIRE BCID2 Panel lot manufactured in the past 12 months, if used with BACT/ALERT Lot# 0004101790, 0004101718, 0004101958, 0004101638 S/N: N/A | | | IVD: Multiple-type bloodstream pathogen nucleic acid IVD, kit, nucleic acid amplification/mass spectrometry | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_03/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_03/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240611_03/documents/3) | | Vk\_20240611\_03 |
| 11.06.2024 | Beckman Coulter Ireland, Inc. | IgM (Immunoglobulin ) Model: OSR61173 | | | IVD: Immunoglobulin M | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_16/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_16/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_16/documents/2) | | Vk\_20240606\_16 |
| 11.06.2024 | Philips Healthcare Enterprise Imaging Informatics | SENSE XL Torso coil (1.5T and 3.0T) Model: 453567141882, 453567141883, 989603014351, 989603014352, | | | MD: Full-body MRI system, superconducting magnet | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_13/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_13/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240606_13/documents/2) | | Vk\_20240606\_13 |
| 11.06.2024 | DH Healthcare GmbH | DeepUnity Diagnost | | | MD: Picture Archiving And Communication Systems | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240605_20/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240605_20/documents/1) | | Vk\_20240605\_20 |
| 11.06.2024 | Radiometer Medical | ABL800 Basic Model: 393-800 Lot: All analyzers S/N: N/A  ABL800 FLEX Model: 393- 801 Lot: All analyzers SW-Version: N/A | | | IVD: Metabolic profile clinical chemistry analyser IVD, stationary, automated  IVD: Metabolic profile clinical chemistry analyser IVD, stationary, automated | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_22/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_22/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_22/documents/2) | | Vk\_20240530\_22 |
| 10.06.2024 | Smiths Medical ASD, Inc. | Bivona Tracheostomy Tubes Model: see FSN Lot: Affected Products List attached | | | MD: Tracheostomy tube, non-reinforced, non-customized, reusable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_27/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_27/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_27/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240610_27/documents/3) | | Vk\_20240610\_27 |
| 28.03.2024  (Updated 10.06.2024) | Philips Respironics, Inc | OmniLab Advanced + Model: Please refer to Device Affected List; NA Lot: NA S/N: Please refer to Device Affected List | | | MD: Ventilator | | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240327_15/documents/0) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240327_15/documents/1) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240327_15/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240327_15/documents/3) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240327_15/documents/4) | | Vk\_20240327\_15 |
| 07.06.2024 | Stryker Neurovascular | Trevo Retrievers/Microcatheters/Synchro Guide wire Model: see FSN Lot: see FSN | | | MD: Thrombectomy suction catheter; Angiographic catheter, single-use; Intravascular occluding ballon catheter, image-guided; cardiac/peripheral vascular guidewire, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240531_23/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240531_23/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240531_23/documents/2) | | Vk\_20240531\_23 |
| 29.05.2024  (Updated 07.06.2024) | BioFire Diagnostics, LLC | BIOFIRE FILMARRAY TORCH Model: Shipping Configuration: HTFA-ASY-0001, Part Number: HTFA-ASY-0104 Lot: All BIOFIRE FILMARRAY TORCH manufactured | | | IVD: Thermal cycler nucleic acid amplification analyser IVD, laboratory | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_26/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_26/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_26/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_26/documents/3) | | Vk\_20240522\_26 |
| 29.05.2024  (Updated 06.06.2024) | Invivoscribe, Inc | LymphoTrack Dx TRG Assay Panel - MiSeq Model: 92270009 Lot: see FSN S/N: n.a.  LymphoTrack Dx IGHV SHM Assay Panel - MiSeq Model: 91210069 Lot: see FSN S/N: n.a.  LymphoTrack Dx IGHV SHM Kit A - MiSeq Model: 91210059 Lot: see FSN S/N: n.a. | | | IVD: Genetic Tests - Other  IVD: Genetic Tests - Other  IVD: Genetic Tests - Other | | [DE-1-IGHV](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/0) [DE-1-IGHV\_TRG](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/1) [DE-1-TRG](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/2) [FR-1-IGHV](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/3) [FR-1-IGHV\_TRG](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/4) [FR-1-TRG](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/5) [IT-1-IGHV](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/6) [EN-1-IGHV](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/7) [EN-1-IGHV\_TRG](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/8) [EN-1-TRG](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_11/documents/9) | | Vk\_20240521\_11 |
| 08.01.2024  (Updated 06.06.2024) | Becton Dickinson Diagnostic Systems | BD Sensi-Disc Model: see FSN Lot: see web-tool of manufacturer | | | IVD: Antibacterial susceptibility testing disc IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240103_04/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240103_04/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240103_04/documents/2) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240103_04/documents/3) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240103_04/documents/4) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240103_04/documents/5) | | Vk\_20240103\_04 |
| 05.06.2024 | Beckman Coulter , Inc. | DxI 9000 Access Immunoassay Analyzer Model: C11137 SW-Version: 1.17.0 and below | | | IVD: Chemiluminescent immunoassay analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240529_15/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240529_15/documents/1) | | Vk\_20240529\_15 |
| 05.06.2024 | Beckman Coulter , Inc. | DxI 9000 Access Immunoassay Analyzer Model: C11137 SW-Version: 1.17 and below | | | IVD: Chemiluminescent immunoassay analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240529_09/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240529_09/documents/1) | | Vk\_20240529\_09 |
| 05.06.2024 | Ganshorn Medizin Electronic GmbH | Provo.X Model: Revision A or Revision B, which had been upgraded to Revision C S/N: see FSN | | | MD: Benchtop nebulizer, non-heated | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_24/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_24/documents/1) | | Vk\_20240524\_24 |
| 04.06.2024 | Philips Medical Systems | Avalon Ultrasound Transducer Model: 867246 | | | MD: Foetal Doppler system probe | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240603_13/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240603_13/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240603_13/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240603_13/documents/3) | | Vk\_20240603\_13 |
| 04.06.2024 | GE Healthcare Finland Oy | Centricity High Acuity Anesthesia / Critical Care | | | MD: Medical image management system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_16/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_16/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_16/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_16/documents/3) | | Vk\_20240530\_16 |
| 04.06.2024 | Getinge Schweiz AG | Advanta VXT and Flixene Vascular Graft Model: see FSN Lot: see FSN SW-Version: NA | | | MD: Ptfe Vascular Prostheses, Straight | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_15/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_15/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240530_15/documents/2) | | Vk\_20240530\_15 |
| 04.06.2024 | DH Healthcare GmbH | ORBIS Medication 3.x SW-Version: 03.15.00.00 | | | MD: General Medicine Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240529_34/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240529_34/documents/1) | | Vk\_20240529\_34 |
| 28.05.2024  (Updated 04.06.2024) | Abbott Diagnostics Technologies AS | Afinion 2 Model: 1116772, 1116774, 1116777, 1116778, 1116770, 1116771, 1117030 S/N: Series AF20052000 to AF20060000 | | | IVD: Single-channel clinical chemistry analyser IVD, point-of-care | | [DE- FR - IT-1 - DISTR](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240528_01/documents/0) [DE- FR - IT-1 - HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240528_01/documents/1) [EN-1 - DISTR](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240528_01/documents/2) [EN-1 - HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240528_01/documents/3) | | Vk\_20240528\_01 |
| 29.05.2024  (Updated 04.06.2024) | Roche Diabetes Care GmbH | RocheDiabetes Care Platform Model: 08888353001 SW-Version: 2.10.1, 2.10.2 | | | MD: General Medicine Diagnosis And Monitoring Instruments - Medical Device Software | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_25/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_25/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_25/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_25/documents/3) | | Vk\_20240527\_25 |
| 28.05.2024  (Updated 04.06.2024) | Biocartis NV | IdyllaTM EGFR Mutation Test Model: A0060/6 | | | IVD: Epidermal growth factor receptor (EGFR) gene mutation/mRNA expression IVD, kit, nucleic acid technique (NAT) | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_18/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_18/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_18/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_18/documents/3) | | Vk\_20240527\_18 |
| 28.05.2024  (Updated 04.06.2024) | LumiraDX UK Ltd | LumiraDx Platform Instrument Model: V5E; L001000303001 S/N: 30874-20-31-05620; 30874-20-31-05741; 30874-20-31-05776; 30874-20-31-05816 | | | IVD: Mixed Panel Multiparameter Analysers - Low Routine (throughput <= 800 Test/h) | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_02/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_02/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_02/documents/2) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_02/documents/3) | | Vk\_20240527\_02 |
| 28.05.2024  (Updated 03.06.2024) | Zoll Medical Corporation | ZOLL 731 Ventilator Model: All Operator's Guides and Quick Reference Guides specific for use with MRI Compatible 731 ZOLL Ventilators | | | MD: Transport electric ventilator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_07/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_07/documents/1) | | Vk\_20240524\_07 |
| 16.04.2024  (Updated 31.05.2024) | ACUTRONIC Medical Systems AG | Fabian HFO Model: 112001 S/N: All SN updated to SW V5.2.2 SW-Version: SW V5.2.2  fabian HFOi Ventilator Model: 113001 S/N: All SN updated to SW V5.2.2 SW-Version: SW V5.2.2 | | | MD: Neonatal intensive-care ventilator  MD: Neonatal intensive-care ventilator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240410_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240410_03/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240410_03/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240410_03/documents/3) | | Vk\_20240410\_03 |
| 28.05.2024  (Updated 30.05.2024) | EIT Emerging Implant Technologies GmbH | EIT Cellular Titanium TLIF & PLIF Cages Model: THI81228, THI80932 Lot: 128956, 128950 | | | MD: Metallic spinal interbody fusion cage | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_08/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_08/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_08/documents/2) | | Vk\_20240517\_08 |
| 30.05.2024 | Balt USA | Optima Coil System Model: see Annex 1 Lot: see Annex 1 | | | MD: Detachable Coil Equipment For Brain Aneurysms | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_02/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_02/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_02/documents/2) | | Vk\_20240515\_02 |
| 29.05.2024 | Fresenius Kabi AG | Exelia SP Model: Z084010 S/N: 24755774, 24785804, 24785791 | | | MD: Bedside syringe pump | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240528_02/documents/0) | | Vk\_20240528\_02 |
| 29.05.2024 | Integra LifeSciences (Ireland) Ltd. | CUSA EXCEL Model: C2600 S/N: All serial numbers distributed from 1st of January 2017 to 14th of December 2023 | | | MD: Soft-tissue ultrasonic surgical system handpiece, reusable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_16/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_16/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_16/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_16/documents/3) | | Vk\_20240527\_16 |
| 29.05.2024 | Thoratec Switzerland GmbH | CentriMag 2nd Generation Primary Console Model: 201-30300, 201-90401, 201-90701, L201-90401, L201-90421 S/N: All serial numbers manufactured after March 21, 2016 | | | MD: Cardiopulmonary bypass system centrifugal pump drive unit | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_21/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_21/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_21/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240522_21/documents/3) | | Vk\_20240522\_21 |
| 29.05.2024 | Cadwell Industries, Inc. | IOMAX Cortical Module Model: 190296-200 S/N: See FSN | | | MD: Nervous System Monitoring Systems | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_02/documents/0) | | Vk\_20240521\_02 |
| 28.05.2024 | GE Vingmed Ultrasound AS | Vivid Model: - Vivid E95/E90/E80 with software version 201, revision 54.0 and 61.0; - Vivid S70/S60 with software version 201, revision 55.0 and 63.0. SW-Version: Software Version 201 | | | MD: Cardiovascular ultrasound imaging system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_04/documents/0) | | Vk\_20240527\_04 |
| 28.05.2024 | SEBIA | CAPI 3 IMMUNOTYPING Model: 2600 Lot: 13034/01 ; 13034/02 ; 13034/03 | | | IVD: Multiple clinical chemistry protein IVD, reagent | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_13/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_13/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240524_13/documents/2) | | Vk\_20240524\_13 |
| 28.05.2024 | Stryker Orthopaedics | Mako Total Knee Model: 700001590415, 700001590414, 700002190743-04, 700002190743-01, 700002190743-03, 700002190743-05 Lot: see FSN | | | MD: Stereotactic Orthopaedic Surgery Instruments - Software Accessories | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_54/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_54/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_54/documents/2) | | Vk\_20240521\_54 |
| 28.05.2024 | GE Healthcare Finland Oy | CARESCAPE Model: See FSN | | | MD: General-purpose multi-parameter bedside monitor | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_19/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_19/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_19/documents/3) | | Vk\_20240507\_19 |
| 27.05.2024 | tecfor care GmbH | Ecofit Xtra 120 Model: 00400 S/N: all serial number from 21 0000000000, to 23 9999999999  Ecofit Xtra 140 Model: 00401 S/N: all serial number from 21 0000000000, to 23 9999999999 | | | MD: Electrical assistive bed  MD: Electrical assistive bed | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_15/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240527_15/documents/1) | | Vk\_20240527\_15 |
| 27.05.2024 | NAUSICAA MEDICAL | NAUSIFLY 180 | | | MD: patient lift | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_09/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240521_09/documents/1) | | Vk\_20240521\_09 |
| 27.05.2024 | Megadyne Medical Products, Inc | MEGADYNE MEGA SOFT Pediatric Patient Return Electrode Model: 0840 Lot: all | | | MD: Electrosurgical return electrode, reusable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_15/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_15/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_15/documents/2) | | Vk\_20240514\_15 |
| 17.05.2024  (Updated 27.05.2024) | Masimo Corporation | TC-I Reusable Tip Clip Sensor Model: 4053 Lot: see FSN  LNCS TC-I, 1/Box, Masimo   Model: 1895 Lot: see FSN  M-LNCS TC-I, 1/Box, Masimo   Model: 2503 Lot: see FSN | | | MD: Pulse oximeter probe, reusable  MD: Pulse oximeter probe, reusable  MD: Pulse oximeter probe, reusable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240508_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240508_19/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240508_19/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240508_19/documents/3) | | Vk\_20240508\_19 |
| 27.05.2024 | Intersurgical Ltd | Mapleson F Anaesthetic Breathing Systems Model: 2120000, 2121000, 2121002, 2121004, 2121005, 2121011, 2121014, 2121019, 2121024, 2121035, 2121042, 2121045, 2121048, 2121053 Lot: Expiry date from April 2024 to March 2029 | | | MD: Anaesthesia breathing circuit, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240502_08/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240502_08/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240502_08/documents/2) | | Vk\_20240502\_08 |
| 24.05.2024 | Datascope Corp. | Cardiosave Intra-Aortic Balloon Pump Model: 0998-XX-0800-XX Lot: All S/N: All Cardiosave serial numbers distributed since March 6, 2012 to present and ongoing | | | MD: Intra-aortic balloon pump | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_03/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_03/documents/2) | | Vk\_20240517\_03 |
| 24.05.2024 | Datascope Corp. | Cardiosave Intra-Aortic Balloon Pump Model: 0998-XX-0800-XX Lot: All S/N: All Cardiosave serial numbers distributed since March 6, 2012 to present and ongoing | | | MD: Intra-aortic balloon pump | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_02/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_02/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240517_02/documents/2) | | Vk\_20240517\_02 |
| 23.05.2024 | DiaSorin S.p.A. | LIAISON BRAHMS PCT II GEN Model: 318040 Lot: 239036 | | | IVD: Procalcitonin (PCT) IVD, kit, chemiluminescent immunoassay | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240508_16/documents/0) | | Vk\_20240508\_16 |
| 23.05.2024 | ATF | PE LIBERTY LINER Model: 43022848, 43022850, 43022852, 43022854, 43022856, 43022858, 43022860 Lot: B1006-231448, B989-231448, B996-231448, B1013-232003, B999-232003, B1006-232005, B999-232005, B1006-232004, B996-232004, B1024-231446, B989-231447, B996-231447, B996-231449, B1006-231449, B999-232002, B1024-232002 | | | MD: Non-constrained polyethylene acetabular liner | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_24/documents/0) | | Vk\_20240507\_24 |
| 22.05.2024 | Philips Medical Systems DMC GmbH | MobileDiagnost wDR Model: 712007, 712006, 712004, 712002, 712005, 9890-010-89522 | | | MD: Mobile basic diagnostic x-ray system, digital | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_26/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_26/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_26/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_26/documents/3) | | Vk\_20240515\_26 |
| 22.05.2024 | Medtronic Inc. | Ascenda Intrathecal Catheter Model: 8780, 8781 Lot: All S/N: All SW-Version: N/A  Ascenda Intrathecal Catheter Pump Segment Revision Kit Model: 8784 Lot: All S/N: All | | | AIMD: Lumbar cerebrospinal fluid drainage catheterization kit  AIMD: Lumbar cerebrospinal fluid drainage catheterization kit | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_24/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_24/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_24/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_24/documents/3) | | Vk\_20240514\_24 |
| 21.05.2024 | Medtronic Inc. | Percept Model: impacts patients who have a pocket adaptor with Percept PC B35200, or Percept RC B35300 that previously used the A610 REPLACEMENT workflow to transfer settings from Activa SC Model 37602. S/N: All  Activa SC Model: impacts patients who currently have an Activa SC Model 37602 implanted and are implanted with a pocket adaptor in the future during an INS replacement, with settings transferred using the A610 REPLACEMENT workflow. S/N: All  DBS Clinician Programmer Application Model: A610 SW-Version: Version 2.0.x (2.0.4584, 2.0.4594, 2.0.4605, 2.0.4630, and 2.0.4648); Version 3.0.x (3.0.1057, 3.0.1062, 3.0.1081, and 3.0.1098); Version 4.0.x (4.0.1052)  DBS Pocket Adaptor Model: 64001 or 64002 S/N: All  Activa SC Model: impacts patients who have a pocket adaptor with Activa SC Model 37603, that previously used the A610 REPLACEMENT workflow to transfer settings from Activa SC Model 37602. S/N: All | | | AIMD: Deep brain electrical stimulation system  AIMD: Deep brain electrical stimulation system  MD: Clinician Programmer Software Application  AIMD: Neural-tissue electrical stimulation lead adaptor  AIMD: Deep brain electrical stimulation system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_33/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_33/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_33/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240515_33/documents/3) | | Vk\_20240515\_33 |
| 21.05.2024 | Johnson & Johnson International | Vicryl and Vicryl Plus Model: Attachment 3 - Product details; Attachment 3 - Product details Lot: Attachment 3 - Product details S/N: Attachment 3 - Product details  PDS (polydioxanone) suture Model: Attachment 3 - Product details; Attachment 3 - Product details Lot: Attachment 3 - Product details; Attachment 3 - Product details  PDS Plus Antibacterial Suture Model: Attachment 3 - Product details; Attachment 3 - Product details Lot: Attachment 3 - Product details; Attachment 3 - Product details  MONOCRYL and MONOCRYL PLUS sutures Model: Attachment 3 - Product details; Attachment 3 - Product details Lot: Attachment 3 - Product details; Attachment 3 - Product details | | | MD: Polyester suture, bioabsorbable, multifilament, non-antimicrobial  MD: Polyester suture, bioabsorbable, monofilament, non-antimicrobial  MD: Polyester suture, bioabsorbable, monofilament, antimicrobial  MD: Polyester suture, bioabsorbable, monofilament, antimicrobial | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_16/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_16/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_16/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240514_16/documents/3) | | Vk\_20240514\_16 |
| 21.05.2024 | Thoratec Corporation | HeartMate System Monitor Model: 1286, L1286, 1286A, L1286A, 1286INT, L1286INT S/N: All serial numbers | | | AIMD: Implantable ventricular circulatory assist system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_03/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_03/documents/2) | | Vk\_20240513\_03 |
| 14.05.2024  (Updated 21.05.2024) | Biosense Webster Inc | VARIPULSE Bi-Directional Catheter Model: D141201 Lot: 31192375L; 31203363L; 31203365L | | | MD: Arrhythmogenic Foci Ablation Leads Via Other Energy Sources | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_23/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_23/documents/1) | | Vk\_20240507\_23 |
| 08.05.2024  (Updated 21.05.2024) | Philips Medical Systems Nederland B.V. | Philips Hemodynamic Application Model: 722467 Lot: Not applicable S/N: 2111600651, 101 SW-Version: 1.2.0, 1.2.1, 1.2.2, 1.2.3, 1.3.0, 1.3.1 | | | MD: Haemodynamic monitoring system application software | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240502_16/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240502_16/documents/1) | | Vk\_20240502\_16 |
| 21.05.2024 | Philips Medical Systems Nederland B.V. | Philips MR systems with g-MDU Model: See FSN | | | MD: Full-body MRI system, superconducting magnet | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240426_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240426_19/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240426_19/documents/2) | | Vk\_20240426\_19 |
| 17.05.2024 | tecfor care GmbH | Ecofit Model: 00124, 00903, 00918, 00203, 00907, 00908, 00200, 00207, 00210, 00212, 00103, 00115, 00100, 00102, 00105, 00106, 00108, 00109, 00110, 00111, 00112, 00113, 00116, 00117, 00120, 00123, 00125, 00126, 00912, 00920, 00900, 00916, 00922 S/N: all serial numbers from 21 0000000000 to 23 9999999999 | | | MD: Electrical assistive bed | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_21/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_21/documents/1) | | Vk\_20240506\_21 |
| 03.05.2024  (Updated 17.05.2024) | Gyrus ACMI Inc. | INSTACLEAR SHEATH Model: see FSN Lot: All | | | MD: Endoscope lens cleaner, gas/fluid, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_02/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_02/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_02/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_02/documents/3) | | Vk\_20240430\_02 |
| 08.12.2023  (Updated 17.05.2024) | Karl Storz SE und Co. KG | BEYER Antrum Punch Model: 615000 Lot: all  Antrum Punch Model: 615010 Lot: all  Sphenoid Punch Model: 615025; 648500; 648523 Lot: all  Galea Spring Hook Model: 662797 Lot: all  Uvula Retractor Model: 723014 Lot: all  Optical Biopsy and Grasping Forceps Model: 723400 Lot: all  Grasping Forceps, flexible Model: 11003MB Lot: all  Optical Scissor Model: 11540OS Lot: all  Working Insert, with steering lever Model: 26161UH Lot: all | | | MD: Bone punch, reusable  MD: Bone punch, reusable  MD: Bone punch, reusable  MD: Hand-held surgical retractor, reusable  MD: Soft-tissue surgical hook, reusable  MD: Flexible endoscopic tissue manipulation forceps, reusable  MD: Surgical soft-tissue manipulation forceps, scissors-like, reusable  MD: Gynaecological scissors, reusable  MD: Rigid endoscope working guide | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/1) [DE-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/2) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/3) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/4) [FR-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/5) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/6) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/7) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/8) [EN-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231204_02/documents/9) | | Vk\_20231204\_02 |
| 16.05.2024 | Fresenius Medical Care AG & Co. KGaA | multiFiltratePRO Model: M205001 SW-Version: Software versions 6.02 and 5.02 | | | MD: Haemodialysis system, institutional/home-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240516_04/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240516_04/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240516_04/documents/2) | | Vk\_20240516\_04 |
| 16.05.2024 | Philips Medical Systems Nederland B.V. | Height Adjustable (HA) FlexTrak Trolley Model: 989710006411, 989710006412, 989710008732 S/N: See FSN | | | MD: Full-body MRI system, superconducting magnet | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_39/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_39/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_39/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_39/documents/3) | | Vk\_20240513\_39 |
| 08.05.2024  (Updated 16.05.2024) | DIALAB - Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. | Phosphorus Inorganic, Molybdate Model: D00359B, D00361, D00362, D00363, D00364, D0435917, D85911, DA0840, DB20329, DE1840. Lot: See FSN | | | IVD: Inorganic phosphate (PO43-) IVD, reagent | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_02/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_02/documents/1) | | Vk\_20240507\_02 |
| 14.05.2024 | SD Biosensor Inc. | STANDARD F2400 Analyzer Model: 10FA24 SW-Version: V001.046 | | | IVD: Fluorescent immunoassay analyser IVD, point-of-care | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_19/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240513_19/documents/1) | | Vk\_20240513\_19 |
| 14.05.2024 | DH Healthcare GmbH | ORBIS Medication 3.x SW-Version: 03.19.01.00 | | | MD: General Medicine Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_25/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_25/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_25/documents/2) | | Vk\_20240507\_25 |
| 14.05.2024 | Roche Diabetes Care GmbH | Accu-Chek Guide (FCN) Kit Model: 07400870016 Lot: 31199447 S/N: 92539374976 | | | IVD: Blood Glucose Meters | | [DE-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_28/documents/0) [DE-1-PAT](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_28/documents/1) [FR-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_28/documents/2) [FR-1-PAT](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_28/documents/3) [IT-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_28/documents/4) [IT-1-PAT](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_28/documents/5) | | Vk\_20240506\_28 |
| 14.05.2024 | Innomed, Inc. | Cup Removal Starter Instrument Model: 5200-54 Lot: 1223K | | | MD: General Surgery Spreaders And Spatulas, Reusable | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240503_01/documents/0) | | Vk\_20240503\_01 |
| 14.05.2024 | Philips Medical Systems Nederland B.V. | Ingenia with Evolution Upgrade Model: 782116, 782117 S/N: 70589, 71044 SW-Version: R5.7.1 | | | MD: Full-body MRI system, superconducting magnet | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240425_10/documents/0) | | Vk\_20240425\_10 |
| 09.05.2024  (Updated 13.05.2024) | Becton, Dickinson and Company, BD Biosciences | BD Multitest 6-Color TBNK Model: 644611, 337166 Lot: See FSN | | | IVD: Antibodies For B And T-cell Subtyping | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240501_20/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240501_20/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240501_20/documents/2) | | Vk\_20240501\_20 |
| 03.05.2024  (Updated 13.05.2024) | Covidien llc | Esoflip Model: ES-330 Lot: see FSN | | | MD: Gastrointestinal/biliary dilation balloon catheter | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240425_13/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240425_13/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240425_13/documents/2) | | Vk\_20240425\_13 |
| 13.05.2024 | Cantel Medical (Italy) S.r.l. | LARAH Hookup Accessory Model: LARAH318 and LARAH340 Lot: LA-RAH340/079; LA-RAH340/080; LA-RAH340/081; 059030/001 | | | MD: Cleaning, Disinfection And Sterilisation Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_02/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_02/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_02/documents/2) | | Vk\_20240424\_02 |
| 09.05.2024 | LumiraDX UK Ltd | LumiraDx Platform Instrument Model: V5E; L001000301001, L001000303001, L001000304001, L001000305001, L001000306001 S/N: 30874-20-31-05753, 30874-20-37-04211, 30874-20-39-09365, 30874-20-41-10678, 30874-20-42-11575, 30874-20-49-16329, 30874-21-04-22269, 30874-22-20-64424 | | | IVD: Mixed Panel Multiparameter Analysers - Low Routine (throughput <= 800 Test/h) | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_01/documents/0) | | Vk\_20240506\_01 |
| 08.05.2024 | Illumina, Inc | NextSeq 550Dx Model: 20005715  MiSeqDx Instrument Model: DX-410-1001  NovaSeq 6000Dx Model: 20068232 | | | IVD: Nucleic acid sequence analyser IVD, next-generation sequencing (NGS)  IVD: Nucleic acid sequence analyser IVD, next-generation sequencing (NGS)  IVD: Nucleic acid sequence analyser IVD, next-generation sequencing (NGS) | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_01/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_01/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_01/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240507_01/documents/3) | | Vk\_20240507\_01 |
| 08.05.2024 | Oriplast GmbH | Schleimabsauger, 450mm, Ch.8, für Neugeborene Model: VK00942 Lot: 03/2022/10, 09/2022/41, 10/2022/49 | | | MD: Mucous Aspirators | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_20/documents/0) [DE-1\_Draeger](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_20/documents/1) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_20/documents/2) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240506_20/documents/3) | | Vk\_20240506\_20 |
| 08.05.2024 | Alcon Laboratories, Inc. | 20G MVR+ V-Lance Ophthalmic knife Model: see attached Lot: see attached SW-Version: N/A  ClearCut knive Model: see attached; see attached Lot: see attached S/N: N/A SW-Version: N/A | | | MD: Ophthalmic knife, single-use  MD: Ophthalmic knife, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_19/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240430_19/documents/2) | | Vk\_20240430\_19 |
| 01.05.2024  (Updated 08.05.2024) | Maquet Critical Care AB | Flow-i C20, Flow-i C30, Flow-i C40, Flow-c, Flow-e Model: 6888520, 6888530, 6888540, 6887700, 6887900 S/N: see FSN | | | MD: Anaesthesia workstation, general-purpose | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_27/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_27/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_27/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_27/documents/3) | | Vk\_20240424\_27 |
| 07.05.2024 | DH Healthcare GmbH | ORBIS Medication 3.x SW-Version: 03.18.03.01 | | | MD: General Medicine Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_42/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_42/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_42/documents/2) | | Vk\_20240429\_42 |
| 06.05.2024 | DH Healthcare GmbH | ORBIS Medication 3.x SW-Version: 03.16.00.00 | | | MD: General Medicine Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_30/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_30/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_30/documents/2) | | Vk\_20240424\_30 |
| 03.05.2024 | Health Information Management GmbH | QCare PDMS Model: 187.3 SW-Version: 5.0.xxx.x to 5.0.187.3 | | | MD: Data management system, patient | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_30/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_30/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_30/documents/2) | | Vk\_20240429\_30 |
| 03.05.2024 | Welch Allyn, Inc. | ProBP 3400 Blood Pressure Device Model: 34XFST-2; PWCD-5WT-2; PWCD-6WT-2 Lot: see FSN  SPOT VISION SCREENER Model: VS100S-2; 106364 Lot: see FSN | | | MD: Automatic-inflation electronic sphygmomanometer, portable, arm/wrist  MD: Vision/eye movement analysis system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_01/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_01/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_01/documents/2) | | Vk\_20240424\_01 |
| 03.05.2024 | Medtronic Inc. | Defibrillator | | | MD: Implantable Single Chamber Defibrillators | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_32/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_32/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_32/documents/2) | | Vk\_20240422\_32 |
| 01.05.2024 | ConforMIS, Inc. | iTotal Patella Trials Model: 1080-509, 1080-510, 1080-511, 1080-512, 1080-513 Lot: All | | | MD: Patella prosthesis trial | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240426_06/documents/0) | | Vk\_20240426\_06 |
| 30.04.2024 | B. Braun Melsungen AG | ARTERIOFIX ART.-KATH.-SET 20G/80MM Model: 5206324 Lot: 23H05844, 23G14844 | | | MD: Angiography kit | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_09/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240429_09/documents/1) | | Vk\_20240429\_09 |
| 30.04.2024 | Beckman Coulter , Inc. | DxI 9000 Access Immunoassay Analyzer Model: C11137 SW-Version: SW 1.13 and higher | | | IVD: Chemiluminescent immunoassay analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_22/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_22/documents/1) | | Vk\_20240424\_22 |
| 30.04.2024 | Dong Guan QueenMed Equipment Mfg Co Ltd | Electrosurgical Electrode Model: See FSN Lot: see FSN | | | MD: Open-surgery electrosurgical handpiece/electrode, monopolar, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_19/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240424_19/documents/2) | | Vk\_20240424\_19 |
| 30.04.2024 | HeartSine Technologies Ltd | HeartSine samaritan PAD 350P/360P/450P/500P Model: SAM 300P, 350P, 360P, 450P, 500P S/N: See FSN | | | MD: Non-rechargeable public semi-automated external defibrillator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_25/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_25/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_25/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_25/documents/3) | | Vk\_20240423\_25 |
| 30.04.2024 | Avanos Medical, lnc. | NeoMed - Oral/Enteral Syringes and Oral Dispensers Model: BA-S1EO, BA-S3EO, BA-S6EO Lot: 20200628, 20200802, 20200825, 20200215, 20191011 | | | MD: ENFit oral/enteral syringe, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_01/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_01/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240423_01/documents/2) | | Vk\_20240423\_01 |
| 23.04.2024  (Updated 29.04.2024) | Medtronic Navigation Inc. | Software App 9735762 Stealth S8 Application Model: 9735762 S/N: All SW-Version: 1.0.1, 1.0.2, 1.0.3, 1.1.0, 1.2.0 | | | MD: Multi-purpose stereotactic surgery system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_26/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_26/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_26/documents/2) | | Vk\_20240417\_26 |
| 02.04.2024  (Updated 29.04.2024) | TATA SURGICAL (PVT) LTD | Sterile Single Use General Surgery Suction Tubes Model: TAYT 10-203N, TAYT 10-205N Lot: 090523/01, 090523/02 | | | MD: Suction/irrigation tubing, single-use | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_34/documents/0) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_34/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_34/documents/2) | | Vk\_20240402\_34 |
| 09.04.2024  (Updated 26.04.2024) | Cepheid | Xpert Carba-R Model: GXCARBARP-CE-10 Lot: Lot 10808 / Batch 1001208183 | | | IVD: Nucleic Acid Identification - Manual / Automated Carbapenemase | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_03/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_03/documents/1) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_03/documents/2) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_03/documents/3) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_03/documents/4) | | Vk\_20240405\_03 |
| 24.04.2024  (Updated 25.04.2024) | The Surgical Company International B.V. | Fluido Trauma set Sterile Model: 671500 Lot: See FSN | | | MD: Radiation blood/fluid warmer intravenous set | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_30/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_30/documents/1) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_30/documents/2) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_30/documents/3) | | Vk\_20240422\_30 |
| 25.04.2024 | General Medical Merate S.p.A. | Clisis Systems S/N: serial number 00811 to serial number 01672 included  EIDOS RF439 S/N: serial number 00811 to serial number 01672 included  Discovery RF180 S/N: serial number 00811 to serial number 01672 included | | | MD: Stationary general-purpose fluoroscopic x-ray system, digital  MD: Stationary general-purpose fluoroscopic x-ray system, digital  MD: Stationary general-purpose fluoroscopic x-ray system, digital | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_13/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_13/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_13/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_13/documents/3) | | Vk\_20240411\_13 |
| 24.04.2024 | Boston Scientific Neuromodulation Corporation | Vercise Genus Model: M365DB12160, M365DB12320 S/N: 100209 - 753347, 100104 - 753200 | | | AIMD: Deep brain electrical stimulation system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240418_15/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240418_15/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240418_15/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240418_15/documents/3) | | Vk\_20240418\_15 |
| 24.04.2024 | Leica Biosystems Nussloch GmbH | HistoCore Pegasus, HistoCore Pegasus Plus Model: 14048858005, 14048858007 S/N: HistoCore Pegasus: G0061 - G0154, G0156 - G0530, G0532 - G0779, G0781, G0782; HistoCore Pegasus Plus: P0061 - P0080, P0082 - P0116, P0119 - P0156, P0158- P0164, P0166 - P0201, P0203 - P0232, P0234 | | | IVD: Tissue processor IVD, automated/semi-automated | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_28/documents/0) | | Vk\_20240417\_28 |
| 24.04.2024 | Philips Healthcare (Suzhou) Co., Ltd. | Philips CT 3500 Model: 728134, 728138, 728139  Incisive CT Model: 728143, 728144, 728146, 728148, 728149, 728151  CT 5300 Model: 728285 | | | MD: Full-body CT system  MD: Full-body CT system  MD: Full-body CT system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_23/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_23/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_23/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_23/documents/3) | | Vk\_20240417\_23 |
| 24.04.2024 | Philips Medical Systems | PIC iX, PIC iX Expand Model: 866389, 866390 SW-Version: 4.X | | | MD: Centralized patient monitor | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_20/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_20/documents/1) [EN-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_20/documents/2) [EN-1-HCP](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240417_20/documents/3) | | Vk\_20240417\_20 |
| 23.04.2024 | Draeger Medical Systems, Inc. | Infinity Acute Care System Model: MS20407 S/N: not relevant - This FSCA involves M500 Infinity Docking Station Rev. 20, 21, and 23 | | | MD: General-purpose multi-parameter bedside monitor | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_20/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_20/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240422_20/documents/2) | | Vk\_20240422\_20 |
| 23.04.2024 | Randox Laboratories Ltd | Randox Evidence MULTISTAT Model: EV4115 Lot: N/A S/N: not limited to certain serial numbers | | | IVD: Multiplex analyser IVD, laboratory | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240419_17/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240419_17/documents/1) | | Vk\_20240419\_17 |
| 16.04.2024  (Updated 22.04.2024) | SpineVision | HEXANIUM TLIF cage-holder Model: All models Lot: All batches | | | MD: Orthopaedic surgical procedure kit, non-medicated, reusable | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_12/documents/0) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_12/documents/1) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_12/documents/2) | | Vk\_20240411\_12 |
| 16.04.2024  (Updated 18.04.2024) | DH Healthcare GmbH | DeepUnity Diagnost | | | MD: Picture Archiving And Communication Systems | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_10/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_10/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_10/documents/2) | | Vk\_20240411\_10 |
| 18.04.2024 | MAQUET Cardiopulmonary GmbH | Leg holder Model: 1003.80A0 S/N: See FSN | | | MD: Leg procedure positioner | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240409_19/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240409_19/documents/1) | | Vk\_20240409\_19 |
| 27.03.2023  (Updated 18.04.2024) | Datascope Corp. | CARDIOSAVE® Hybrid Intra-Aortic Balloon Pump Model: 0998-00-0800-XX, 0998-UC-0800-XX Lot: N/A S/N: All Cardiosave serial numbers distributed March 6, 2012 to present | | | MD: Intra-aortic balloon pump | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/1) [DE-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/2) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/3) [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/4) [FR-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/5) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/6) [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/7) [IT-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/8) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20230327_30/documents/9) | | Vk\_20230327\_30 |
| 17.04.2024 | Beldico S.A./N.V | Sampling Site Connector Model: HPF0574 Lot: 21J29, 23E05, 22J07  6 Lead Pooling + 3L Bag Model: HPF0611 Lot: 21G16  2 Spike to Membrane Port Model: HPF7089 Lot: 20L18 | | | MD: Blood washing/centrifugation bag  MD: Blood washing/centrifugation bag  MD: Blood washing/centrifugation bag | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240415_16/documents/0) | | Vk\_20240415\_16 |
| 17.04.2024 | Zimmer, Inc. | NexGen CR-Flex femoral component Model: 00-5952-015-01, 00-5952-015-02, 00-5952-015-05, 00-5952-015-06 Lot: see FSN | | | MD: Coated knee femur prosthesis | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240412_24/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240412_24/documents/1) | | Vk\_20240412\_24 |
| 16.04.2024 | Medartis AG | 2.8 TriLock Screw 22mm, HD7, 1/Pkg Model: A-5850.22/1 Lot: 24377397 | | | MD: Orthopaedic bone screw (non-sliding) | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240415_01/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240415_01/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240415_01/documents/2) | | Vk\_20240415\_01 |
| 16.04.2024 | Integra Pain Management | Integra Cranial Access Kit without drugs Model: INS5HND Lot: 7312131, 7291974, 7291975, 7289690, 7312137, 7312139 | | | MD: Craniotomy kit | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240412_13/documents/0) | | Vk\_20240412\_13 |
| 16.04.2024 | Smiths Medical ASD, Inc. | Portex Blue Line Siliconised PVC Tracheotomy Tube Model: 100/506/045, 100/506/050 Lot: 3814894, 3867128, 3876209, 3876205, 3897842, 4068699, 4187263, 4197391, 4206469 | | | MD: Tracheostomy tube, non-reinforced, non-customized, single-use | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_11/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_11/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_11/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240411_11/documents/3) | | Vk\_20240411\_11 |
| 16.04.2024 | Cook Ireland Limited | EchoTip Ultra HD Ultrasound Access Needle Lot: See FSN  ECHOTIP ULTRA ENDOSCOPIC ULTRASOUND NEEDLE Model: ECHO-19, ECHO-HD-19-A; G31520, G52012 Lot: C2145003, C2144407 SW-Version: N/A | | | MD: General-purpose endoscopic needle, single-use  MD: Ultrasound aspiration biopsy procedure kit | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_09/documents/0) | | Vk\_20240402\_09 |
| 15.04.2024 | Horiba ABX SAS | ABX Pentra Urea CP Model: A11A01641 / 1220001641 Lot: 032608446, 032608447, 032608448, 032608504, 032608539, 032608595, 032608651 | | | IVD: Urea IVD, kit, enzyme spectrophotometry | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_26/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_26/documents/1) | | Vk\_20240403\_26 |
| 28.03.2024  (Updated 10.04.2024) | Tecres S.p.A. | MectaCem-X HV with gentamicin Model: 65.01.111 Lot: 23TC0019, 23TC0020, 23TC0021, 23TC0025, 23TC0026, 23TC0030, 23TC0033, 23TC0035  MectaCem-X LV mit Gentamicin Model: 65.01.113 Lot: 23TC0027 | | | MD: Orthopaedic Prostheses Cements And Accessories For Mixing  MD: Orthopaedic Prostheses Cements And Accessories For Mixing | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_05/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_05/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_05/documents/2) | | Vk\_20240315\_05 |
| 09.04.2024 | Philips Medical Systems | Electric power supply Model: 120V -SCL500RM1U, 230V -SCL500RMI1U | | | MD: Basic power supply, reusable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240408_29/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240408_29/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240408_29/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240408_29/documents/3) | | Vk\_20240408\_29 |
| 09.04.2024 | The Binding Site Group Limited | EXENT analyser Model: IE800 SW-Version: 1.0.13 und 1.0.14 | | | IVD: Mass spectrometry analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_19/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_19/documents/2) | | Vk\_20240405\_19 |
| 09.04.2024 | ViennaLab Diagnostics GmbH | StripAssay Model: 4-160; 4-210 Lot: 90-ZW-24-009, 20-EI-24-001, 20-EI-24-034 SW-Version: n.a. | | | IVD: Human diagnostic assays for genotyping mutations and polymorphisms | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240405_13/documents/0) | | Vk\_20240405\_13 |
| 09.04.2024 | CompuGroup Medical Software GmbH | CGM CLINICAL Medication SW-Version: 8.0-2023CW38, 8.0-2023CW20, 8.0-2021CW45, 8.0-2022CW03, 8.0-2022CW18, 8.0-2022CW27, 9.1-CW44 | | | MD: Medical Device Software - Not Included In Other Classes | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_21/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_21/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_21/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_21/documents/3) | | Vk\_20240404\_21 |
| 09.04.2024 | CompuGroup Medical Software GmbH | CGM CLINICAL Medication SW-Version: 8.0-2023CW38, 8.0-2023CW20, 8.0-2021CW45, 8.0-2022CW03, 8.0-2022CW18, 8.0-2022CW27, 9.1-CW44 | | | MD: Medical Device Software - Not Included In Other Classes | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_12/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_12/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_12/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_12/documents/3) | | Vk\_20240404\_12 |
| 09.04.2024 | CAIR LGL | Suction Tubing in soft PVC SOFTUB Model: TA 57 Lot: 23I01-T | | | MD: Suction/irrigation tubing, single-use | | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_15/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_15/documents/1) | | Vk\_20240403\_15 |
| 09.04.2024 | Abbott Medical | Aveir Leadless Pacemaker, Right Ventricle Model: LSP112V S/N: All current serial numbers SW-Version: Firmware version 19.05.00 for LSP112V | | | MD: Intracardiac pacemaker | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_14/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_14/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_14/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_14/documents/3) | | Vk\_20240403\_14 |
| 09.04.2024 | Masimo Corporation | Rad-G Pulse Oximeter Model: 9849, 9847, 9895, 9210 S/N: see FSN SW-Version: 9847/9849 - v. 1.0, 9210/9895 - v. 1.2 | | | MD: Pulse oximeter | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_03/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_03/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240403_03/documents/2) | | Vk\_20240403\_03 |
| 09.04.2024 | Atrium Medical Corporation | Express Mini 500 Dry Seal Chest Drain Model: 16400 Lot: All | | | MD: Cardiotomy reservoir | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_40/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_40/documents/1) | | Vk\_20240402\_40 |
| 09.04.2024 | Agilent Technologies Singapore Pte Ltd. | Dako CoverStainer, Dako CoverStainer CPO Model: CS10030, CS10040, CS10026, CS10026E; CS100 S/N: all | | | IVD: Microscope slide stainer IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_37/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_37/documents/1) | | Vk\_20240402\_37 |
| 04.04.2024  (Updated 08.04.2024) | Mathys Ltd Bettlach | Affinis Inverse Drill bit 2.5, Gen2 and 3.2, Gen2 Model: 61.34.0184 and 61.34.0185 Lot: For 61.34.0184 all batches lower than 2277885 , , For 61.34.0185 all batches lower than 2277886 | | | MD: Joint prosthesis implantation kit, reusable | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_33/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_33/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_33/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_33/documents/3) | | Vk\_20240326\_33 |
| 05.04.2024 | Smiths Medical ASD, Inc. | Medfusion 3500 and 4000 Syringe Pumps | | | MD: Bedside infusion pump, single-channel | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_20/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_20/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_20/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240404_20/documents/3) | | Vk\_20240404\_20 |
| 05.04.2024 | MAQUET Cardiopulmonary GmbH | CARDIOHELP-i Model: 701048012 S/N: 90410089, 90410122 | | | MD: Cardiopulmonary bypass system, roller type | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_18/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_18/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_18/documents/2) | | Vk\_20240326\_18 |
| 05.04.2024 | FH INDUSTRIE | EASYMOVE CURVED SAWBLADES Model: 270666, 270667, 270668 Lot: see FSN | | | MD: Orthopaedic prosthesis implantation positioning instrument, reusable | | [DE-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240325_31/documents/0) [FR-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240325_31/documents/1) [IT-1-DIST](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240325_31/documents/2) | | Vk\_20240325\_31 |
| 19.03.2024  (Updated 05.04.2024) | Randox Laboratories Ltd | CALIBRATION SERUM LEVEL 3 (CAL 3) Model: CAL2351; CAL10388 Lot: 1260UE, 1262UE, 1295UE, 1297UE, 1298UE, 1315UE, 1325UE, 1326UE; 1295UE, 1325UE | | | IVD: Multiple-type clinical chemistry analyte profile IVD, calibrator | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_19/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_19/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_19/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240315_19/documents/3) | | Vk\_20240315\_19 |
| 17.11.2023  (Updated 05.04.2024) | Becton Dickinson Diagnostic Systems | BD BACTEC MicroMGIT Calibration Vial Model: 441049 Lot: 2067938, 2209320, 326593 | | | IVD: Blood culture analyser IVD | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231108_30/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231108_30/documents/1) [DE-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231108_30/documents/2) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20231108_30/documents/3) | | Vk\_20231108\_30 |
| 22.12.2020  (Updated 05.04.2024) | HeartWare Inc. | HeartWare Ventricular Assist System - HVAD Pump Implant Kit Model: 1104 S/N: all | | | AIMD: Implantable ventricular circulatory assist system | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/1) [DE-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/2) [DE-4](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/3) [DE-5](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/4) [DE-6](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/5) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201218_18/documents/6) | | Vk\_20201218\_18 |
| 11.03.2024  (Updated 04.04.2024) | Philips Medical Systems | Care Event Model: 866435, 866436  Patient Information Center iX Model: 866389, 866390, 866424 | | | MD: Hospital-administration information system  MD: Centralized patient monitor | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240308_21/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240308_21/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240308_21/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240308_21/documents/3) | | Vk\_20240308\_21 |
| 03.04.2024 | Karl Storz SE und Co. KG | LASER Application Instrument Model: 8694 Lot: all  LEUNIG-GREVERS LASER Application Model: 461000 Lot: all | | | MD: Rigid endoscope working guide  MD: Rigid endoscope working guide | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240328_21/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240328_21/documents/1) [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240328_21/documents/2) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240328_21/documents/3) | | Vk\_20240328\_21 |
| 03.04.2024 | Siemens Healthcare GmbH | Artis zee/Q/Q.zen systems Model: see enclosure; see enclosure S/N: Artis zee / Q / Q.zen systems without a coolant level sensor | | | MD: Stationary angiographic x-ray system, digital | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_34/documents/0) [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_34/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_34/documents/2) | | Vk\_20240326\_34 |
| 03.04.2024 | Philips Ultrasound, Inc. | Philips-5000 Compact Series Ultrasound Systems Model: 795141, 795145 S/N: USO23P2069, US823P1231 | | | MD: General-purpose ultrasound imaging system | | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_15/documents/0) | | Vk\_20240326\_15 |
| 02.04.2024 | Diagnostica Stago | STA-R Evolution Model: All references S/N: All analyzers using Microtubes Greiner Minicollect 1.0ml (ref.450539) and/or ISS PAED44 0.8ml in a microtainer rack with screw microtainer adaptor.  STA R Max Model: All references S/N: All analyzers using Microtubes Greiner Minicollect 1.0ml (ref.450539) and/or ISS PAED44 0.8ml in a microtainer rack with screw microtainer adaptor.  STA Compact Max Model: All references S/N: All analyzers using Microtubes Greiner Minicollect 1.0ml (ref.450539) and/or ISS PAED44 0.8ml in a microtainer rack with screw microtainer adaptor. | | | IVD: Coagulation analyser IVD, laboratory  IVD: Coagulation analyser IVD, laboratory  IVD: Coagulation analyser IVD, laboratory | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_31/documents/0) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240402_31/documents/1) | | Vk\_20240402\_31 |
| 02.04.2024 | Catell AB | Catell Armsling Standard Model: BA110-X Lot: 201222, 160922, 120723, 161123  Catell Armsling Abduction Model: BA140-X Lot: 280122, 160322, 200923 | | | MD: Shoulder Orthoses  MD: Shoulder Orthoses | | [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240326_06/documents/0) | | Vk\_20240326\_06 |
| 05.03.2024  (Updated 02.04.2024) | DH Healthcare GmbH | ORBIS Medication 3.x SW-Version: 03.07.00.00 | | | MD: General Medicine Instruments - Other | | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240227_21/documents/0) [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240227_21/documents/1) [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240227_21/documents/2) [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20240227_21/documents/3) | | Vk\_20240227\_21 |