**Інформація, отримана з іноземних систем повідомлення про продукцію, що становить серйозний ризик, за період 01.07.2022 – 30.09.2022**

**Швейцарія**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 23.09.2022  (Updated 30.09.2022) | CareDx AB | Olerup QTYPE 11  Model: 201.701-03/10  Lot: E050; E051; E053; E054; E055; E056; E057; E058; E059; E060; E061 | IVD: Hla Antigen Typing | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220923_18/documents/0)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220923_18/documents/1)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220923_18/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220923_18/documents/3) | Vk\_20220923\_18 |
| 27.09.2022  (Updated 29.09.2022) | Siemens Healthcare Diagnostics Inc. | Lithium (Li) reagents  Model: Atellica CH Lithium (Li) 11097535  Lot: all  Lithium\_2 (LITH\_2) reagents  Model: Atellica CH Lithium\_2 (LITH\_2) 11532401  Lot: all | IVD: Lithium therapeutic drug monitoring IVD, kit, atomic spectroscopy  IVD: Lithium therapeutic drug monitoring IVD, kit, atomic spectroscopy | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220921_10/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220921_10/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220921_10/documents/2) | Vk\_20220921\_10 |
| 28.09.2022 | Synthes GmbH | BME SPEED Implant Kit  Model: SE-1512, SE-0910, SE-1512; SE1512, SE0910, SE1512  Lot: MSE210184; MSE210240; MSE220445  SW-Version: Not applicable  SPEEDSHIFT COMP IMPL KIT  Model: SE-2020-10; SE202010  Lot: MSE210237 | MD: Orthopaedic bone staple, non-adjustable  MD: Orthopaedic bone staple, non-adjustable | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220927_18/documents/0) | Vk\_20220927\_18 |
| 28.09.2022 | Gambro Industries | PRISMAFLEX set  Model: HF20; ST100; ST150; ST60; 109841; 107643; 107636; 107640  Lot: See FSN | MD: Haemofilter | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220921_13/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220921_13/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220921_13/documents/2) | Vk\_20220921\_13 |
| 27.09.2022 | Oxoid Deutschland GmbH, Thermo Fisher Scientific | Columbia CAP Agar with Sheep Blood  Model: PB5082A  Lot: 3532554 | IVD: Enriched agar culture medium IVD | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220920_20/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220920_20/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220920_20/documents/2) | Vk\_20220920\_20 |
| 12.07.2022  (Updated 27.09.2022) | Hitachi High-Tech Corporation | cobas pure sample supply unit  Model: 09031537001  SW-Version: cobas pure system SW : Version 01-01 and 01-02 (09458115001)  cobas pro sample supply unit  Model: 08464502001  SW-Version: cobas pro INSTALL SW : Version 01-01 to 02-02 (09400915001)  cobas pure e 402 analytical unit  Model: 09031553001  SW-Version: cobas pure system SW : Version 01-01 and 01-02 (09458115001)  cobas e 801 analytical unit  Model: 08454345001  SW-Version: cobas pro INSTALL SW : Version 01-01 to 02-02 (09400915001); Install CD c8000 SW: Version 06-01 to 06-08 (09188584001)  cobas e 801 module  Model: 07682913001  SW-Version: cobas pro INSTALL SW : Version 01-01 to 02-02 (09400915001); Install CD c8000 SW: Version 06-01 to 06-08 (09188584001)  cobas pro SSU  Model: 09205632001  SW-Version: cobas pro INSTALL SW : Version 01-01 to 02-02 (09400915001)  cobas 8000 core unit  Model: 05641446001  SW-Version: Install CD c8000 SW: Version 06-01 to 06-08 (09188584001) | IVD: Integrated / Modular Chemistry / Immunochemistry Instruments - Other  IVD: Multi-modality clinical specimen analysis system IVD  IVD: Integrated / Modular Chemistry / Immunochemistry Instruments - Other  IVD: Automated Immunochemistry Analysers - Moderate To High Routine (throughput > 250 And <= 700 Test/h)  IVD: Chemiluminescent immunoassay analyser IVD  IVD: Integrated / Modular Chemistry / Immunochemistry Instruments - Other  IVD: Integrated / Modular Chemistry / Immunochemistry Instruments - Other | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/1)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/2)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/3)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/4)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/5)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/6)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_01/documents/7) | Vk\_20220711\_01 |
| 09.03.2021  (Updated 26.09.2022) | HeartWare Inc. | HeartWare Ventricular Assist System - HVAD Pump Implant Kit  Model: Controller (1401, 1403, 1407, 1420), Battery (1650DE), Controller AC Adapter (1425, 1430), Controller DC Adapter (1440), Alarm Adapter (1450), Data Cable (1575)  Lot: n/a  S/N: All  SW-Version: n/a | AIMD: Implantable ventricular circulatory assist system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/1)  [DE-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/2)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/3)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/4)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/5)  [EN-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210305_06/documents/6) | Vk\_20210305\_06 |
| 23.09.2022 | Johnson and Johnson Surgical Vision, Inc. | Veritas Advanced Infusion Packs  Model: VRT-AI  Lot: See FSN | MD: Surgical irrigation/aspiration tubing set | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220916_18/documents/0) | Vk\_20220916\_18 |
| 20.09.2022  (Updated 23.09.2022) | Siemens Healthcare Diagnostics Inc. | CLINITEK Novus PRO 12 Urinalysis Cassette  Model: 10634644, 10697848  Lot: all | IVD: Multiple urine analyte IVD, kit, colorimetric dipstick, rapid | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_19/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_19/documents/1) | Vk\_20220913\_19 |
| 22.09.2022 | Siemens Healthcare GmbH | ARTIS pheno  SW-Version: VE10B | MD: Stationary angiographic x-ray system, digital | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220920_04/documents/0) | Vk\_20220920\_04 |
| 21.09.2022 | Farapulse Inc. | FARAWAVE Pulsed Field Ablation Catheter  Model: 41M401, 41M402; 00810087180096, 00810087180102  Lot: All  FARASTAR Pulsed Field Ablation Generator  Model: 61M401; 00810087180126  Lot: All | MD: Cardiac irreversible electroporation system catheter  MD: Cardiac irreversible electroporation system catheter | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220916_13/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220916_13/documents/1) | Vk\_20220916\_13 |
| 21.09.2022 | Löwenstein Medical SE & Co. KG | elisa 600, elisa 800 und elisa 800 vit | MD: Intensive care ventilator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_22/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_22/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_22/documents/2) | Vk\_20220913\_22 |
| 14.09.2022  (Updated 20.09.2022) | Roche Molecular Systems, Inc. | cobas 5800 Instrument  Model: 08707464001  SW-Version: N/A | IVD: Nucleic Acid Testing Integreted Extration /amplification /detection Systems | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_23/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_23/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220913_23/documents/2) | Vk\_20220913\_23 |
| 08.12.2020  (Updated 19.09.2022) | Siemens Healthcare Diagnostics Inc | ADVIA GGT reagent  Model: 10309495 (20ml); 10316298 (70ml)  Lot: see FSN  Atellica GGT reagent  Model: 11097597  Lot: see FSN | IVD: Gamma-glutamyltransferase (GGT) IVD, kit, enzyme spectrophotometry  IVD: Gamma-glutamyltransferase (GGT) IVD, kit, enzyme spectrophotometry | [DE-1\_ADVIA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/0)  [DE-1\_Atellica](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/1)  [DE-2\_ADVIA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/2)  [DE-2\_Atellica](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/3)  [FR-1\_Atellica](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/4)  [FR-2\_ADIVA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/5)  [FR-2\_Atellica](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/6)  [EN-2\_ADVIA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/7)  [EN-2\_Atellica](https://fsca.swissmedic.ch/mep/api/publications/Vk_20201130_13/documents/8) | Vk\_20201130\_13 |
| 16.09.2022 | Gelita Medical GmbH | GELITA TUFT-IT  Model: GF-7365; GF-7336  Lot: All lots with shelf-life | MD: Gelatin haemostatic agent | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220912_09/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220912_09/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220912_09/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220912_09/documents/3) | Vk\_20220912\_09 |
| 31.08.2022  (Updated 16.09.2022) | MicroPort CRM S.r.l. | XFINE  Model: XFine JX24D MRI, XFine JX25D MRI, XFine TX25D MRI, XFine TX26D MRI; TLD056C, TLD057C, TLD054C, TLD055C  S/N: See FSN | AIMD: Endocardial pacing lead | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/1)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/2)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/3)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/4)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/5)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/6)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_01/documents/7) | Vk\_20220830\_01 |
| 15.09.2022 | Abbott Vascular | MitraClip G4 Clip Delivery System, MitraClip NTR/XTR Clip Delivery System, TriClip NT/XT Clip Delivery System, and TriClip G4 Clip Delivery System  Model: All model numbers  Lot: All lots  S/N: N/A  SW-Version: N/A | MD: Heart valve clip | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220907_03/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220907_03/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220907_03/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220907_03/documents/3) | Vk\_20220907\_03 |
| 30.08.2022  (Updated 15.09.2022) | Philips Medical Systems (Cleveland), Inc. | Pinnacle3 Radiation Therapy Planning System  Model: 870231, 870237  SW-Version: 16.0.4, 16.4.2, 16.4.3, 16.4.6, 18.0.1 | MD: Radiation therapy software | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220825_04/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220825_04/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220825_04/documents/2) | Vk\_20220825\_04 |
| 26.08.2022  (Updated 15.09.2022) | Leica Microsystems (Schweiz) AG | Arveo  Model: 10448999  S/N: manufactured between July 01st, 2021 and June 8th, 2022  SW-Version: not applicable  ARveo 8  Model: 10449063  S/N: manufactured between July 01st, 2021 and June 8th, 2022  Leica M530 OHX  Model: 10448737, 10448700, 10448704  S/N: manufactured between July 01st, 2021 and June 8th, 2022  PROvido  Model: 10448976, 10448950  S/N: manufactured between July 01st, 2021 and June 8th, 2022 | MD: General-purpose surgical microscope  MD: Operative Microscopes  MD: Neurosurgical microscope  MD: General-purpose surgical microscope | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_27/documents/0)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_27/documents/1)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_27/documents/2)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_27/documents/3) | Vk\_20220819\_27 |
| 23.11.2021  (Updated 15.09.2022) | Medtronic Navigation Inc. | Synergy Cranial, StealthStation Cranial  Model: 9733763, 9735585  Lot: -  S/N: All  SW-Version: 2.2.8; 3.1.1; 3.1.2; 3.1.3 | MD: Neurological stereotactic surgery system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211117_28/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211117_28/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211117_28/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211117_28/documents/3)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211117_28/documents/4) | Vk\_20211117\_28 |
| 14.09.2022 | SenTec AG | NeoContactAgent  Model: 1ST232-100; 1ST230-100  Lot: see FSN | MD: Impedance pneumograph monitor | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220907_19/documents/0) | Vk\_20220907\_19 |
| 17.08.2022  (Updated 14.09.2022) | Respironics, Inc | Amara View  Model: See FSN  DreamWisp  Model: See FSN  DreamWear  Model: See FSN  Wisp  Model: See FSN  Therapy Mask 3100  Model: See FSN | MD: CPAP/BPAP face mask, reusable  MD: CPAP/BPAP nasal mask, reusable  MD: CPAP/BPAP face mask, reusable  MD: CPAP/BPAP nasal mask, reusable  MD: CPAP/BPAP nasal mask, reusable | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220817_09/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220817_09/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220817_09/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220817_09/documents/3) | Vk\_20220817\_09 |
| 13.09.2022 | Datex-Ohmeda Inc. | Aisys CS2  Model: 1011-9050-000  S/N: See FSN  Avance CS2  Model: 1009-9050-000  S/N: See FSN  Avance CS2 Pro  Model: 1009-9050-000  S/N: See FSN | MD: Anaesthesia workstation, general-purpose  MD: Anaesthesia workstation, general-purpose  MD: Anaesthesia workstation, general-purpose | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220907_17/documents/0) | Vk\_20220907\_17 |
| 06.09.2022  (Updated 12.09.2022) | CareDx AB | Olerup QTYPE 11  Model: see FSN  Lot: see FSN | IVD: HLA class I & II antigen tissue typing IVD, kit, multiplex | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220901_24/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220901_24/documents/1) | Vk\_20220901\_24 |
| 07.09.2022 | BS Medical Tech Industry Sarl | Flocare® Safety+ GT /-Suction  Model: CH 12, CH 14; 673803, 673802, 673801  Lot: See FSN  Flocare DirectPEG  Model: CH 12, CH 14; 656893, 656707  Lot: See FSN | MD: Gastro-jejunostomy, Tubes And Sets  MD: Gastro-jejunostomy, Tubes And Sets | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220905_05/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220905_05/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220905_05/documents/2) | Vk\_20220905\_05 |
| 06.09.2022 | Ortho Clinical Diagnostics | VITROS Immunodiagnostic Products HIV Combo Calibrators  Model: 6842780  Lot: see FSN  VITROS Immunodiagnostic Products HIV Combo Reagent Pack  Model: 6842779  Lot: see FSN | IVD: HIV1/HIV2 antigen/antibody IVD, kit, chemiluminescent immunoassay  IVD: HIV1/HIV2 antigen/antibody IVD, kit, chemiluminescent immunoassay | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220905_04/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220905_04/documents/1) | Vk\_20220905\_04 |
| 06.09.2022 | Datex-Ohmeda Inc. | Avance CS2  Model: See FSN  Avance CS2 Pro  Model: See FSN  Aisys CS2  Model: See FSN | MD: Anaesthesia workstation, general-purpose  MD: Anaesthesia workstation, general-purpose  MD: Anaesthesia workstation, general-purpose | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220901_16/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220901_16/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220901_16/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220901_16/documents/3) | Vk\_20220901\_16 |
| 31.08.2022  (Updated 01.09.2022) | Medtronic Inc. | Prevail Paclitaxel-coated PTCA Balloon Catheter  Model: See Appendix A, FSN  Lot: See Appendix A, FSN | MD: Coronary angioplasty balloon catheter, drug-coated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_02/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_02/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220830_02/documents/2) | Vk\_20220830\_02 |
| 01.09.2022 | Spiggle & Theis Medizintechnik GmbH | ENT single-use suction tubes  Model: 3010025, 3010030, 3010040  Lot: 20181130 | MD: Suction Tips, General-Purpose | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220816_12/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220816_12/documents/1) | Vk\_20220816\_12 |
| 25.08.2022  (Updated 31.08.2022) | Bonebridge AG | TAMINA  Model: all  Lot: all | MD: Bone Fixation Plates | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_02/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_02/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_02/documents/2) | Vk\_20220822\_02 |
| 23.08.2022  (Updated 31.08.2022) | Mallinckrodt Pharmaceuticals Ireland Limited | THERAKOS CELLEX Photopheresis System  Model: CLXECP  Lot: K257 | MD: Photopheresis system blood set | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_12/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_12/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_12/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_12/documents/3) | Vk\_20220819\_12 |
| 31.08.2022 | Medline International France SAS | Sterile Surgical Gowns  Model: NS-S3510P; NS-S3513P; NS-S3540P; NS-S3581P; S3500P  Lot: see FSN  SW-Version: N/A | MD: Surgical gown, single-use | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220817_16/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220817_16/documents/1) | Vk\_20220817\_16 |
| 30.08.2022 | Siemens Healthcare Diagnostics Products GmbH | N Antiserum to Human IgG  Model: see FSN  Lot: see FSN | IVD: Total immunoglobulin G (IgG total) IVD, kit, nephelometry/turbidimetry | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220824_01/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220824_01/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220824_01/documents/2) | Vk\_20220824\_01 |
| 29.08.2022  (Updated 30.08.2022) | MELAG Medizintechnik GmbH & Co. KG | Careclave 618  Model: ME10618  S/N: up to 20226181185 | MD: Cleaning, Disinfection And Sterilisation Instruments | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_22/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_22/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_22/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_22/documents/3) | Vk\_20220822\_22 |
| 24.08.2022  (Updated 30.08.2022) | bioMérieux SA | VIDAS 3 SOFTWARE  Model: 423694  SW-Version: 1.4.0 and 1.4.1 | IVD: Fluorescent immunoassay analyser IVD, laboratory, automated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_20/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_20/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_20/documents/2) | Vk\_20220819\_20 |
| 24.08.2022  (Updated 29.08.2022) | Siemens Healthcare Diagnostics Inc. | Dimension Magnesium (MG) Flex reagent cartridge  Model: 10444963/DF57  Lot: FA2350, FA2356, GA2363, FA3019 | IVD: Magnesium (Mg2+) IVD, kit, spectrophotometry | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_01/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_01/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_01/documents/2) | Vk\_20220822\_01 |
| 26.08.2022 | Omnyx, LLC | Dynamyx Digital Pathology Software  SW-Version: 2.x.x | IVD: Pathology information system application software | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_17/documents/0) | Vk\_20220822\_17 |
| 26.08.2022 | Cook Incorporated | Double Flexible Tipped Wire Guide  Model: TDOC-35-145-0-3  Lot: 14793053  Fixed Core Wire Guide (Safe-T-J® Curved)  Model: TSCF-35-145-3; TSCF-35-80-3  Lot: 14831157, 14826198, 14831162, 14826199, 14831159; 14814971  Fixed Core Wire Guide (Straight)  Model: TSF-35-145  Lot: 14833117, 14809680, 14821850, 14827356, 14833110, 14827353, 14821851, 14821849, 14821854  Cope Mandril Wire Guide (Nitinol)  Model: PMG-18SP-60-COPE-NT  Lot: 14816750, 14816754  Vinyl Connecting Tube  Model: CTU14.0-30; CTU14.0-40-ST  Lot: NS14831012, NS14816264, NS14816265; NS14818298  Roadrunner Hydrophilic PC Wire Guide  Model: RPC-035145-0-5; RPC-035145-5; RPC-038145-0-5  Lot: 14769270X, 14828629, 14818489, 14802181, 14818488, 14816224; 14770872; 14804972, 14809971 | MD: Peripheral vascular guidewire, manual  MD: Peripheral vascular guidewire, manual  MD: Peripheral vascular guidewire, manual  MD: Peripheral vascular guidewire, manual  MD: Low-pressure tubing connector, single-use, sterile  MD: Peripheral vascular guidewire, manual | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_11/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_11/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_11/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_11/documents/3) | Vk\_20220818\_11 |
| 26.08.2022 | Haag-Streit AG | Connector Box of Imaging Module IM 910  Model: CB01; 1023640  Lot: 014952008; 014919686; 014828063; 014828063  S/N: 111; 112; 149; 150  SW-Version: N/A | MD: Ophtalmology Assessments And Diagnosis Instruments | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220809_06/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220809_06/documents/1) | Vk\_20220809\_06 |
| 12.08.2022  (Updated 26.08.2022) | CooperVision Manufacturing Limited | All in one light (and branded variants)  Model: CLC001  Lot: 162046 | MD: Multi-purpose soft/rigid contact lens solution | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_14/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_14/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_14/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_14/documents/3) | Vk\_20220804\_14 |
| 25.08.2022 | Becton Dickinson GmbH | Sabouraud Agar with Gentamycin and Chloramphenicol  Model: 254041; 254096  Lot: 2150314; 2172776  Sabouraud Agar with Chloramphenicol  Model: 254091  Lot: 2159395; 2172774  Sabouraud GC Agar / BBL CHROMagar Candida Medium (Biplate)  Model: 254515  Lot: 2152631 | IVD: Differential/selective agar culture medium IVD  IVD: Differential/selective agar culture medium IVD  IVD: Multiple formulation agar culture medium IVD | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_05/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_05/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220822_05/documents/2) | Vk\_20220822\_05 |
| 01.07.2022  (Updated 25.08.2022) | Integra LifeSciences Corp | CereLink ICP Monitor  Model: 826820  S/N: All serial numbers ranging from CLK2111003 to CLK2215542 | MD: Intracranial pressure monitor | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/0)  [DE-4](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/1)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/2)  [FR-4](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/3)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/4)  [IT-4](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/5)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/6)  [EN-3 Extension-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/7)  [EN-4](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_01/documents/8) | Vk\_20220628\_01 |
| 24.08.2022 | Planer Limited | Humidifier Bottle and Syringe filter kit for BT37  Model: AY102295, AY200246  Lot: see FSN | MD: Non-heated respiratory humidifier | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_17/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_17/documents/1) | Vk\_20220815\_17 |
| 23.08.2022 | B. Braun Melsungen AG | SpaceStation with SpaceCom  Model: 8713142  SW-Version: 011L0000L81 and earlier  SpaceCom  Model: 8713160  SW-Version: 011L0000L81 and earlier  Battery-Pack SP (Li-Ion) incl. pin and WiFi  Model: 8713182A  SW-Version: 027L0000L81 and earlier  Data module compactplus  Model: 8717160  SW-Version: I0050A0010 | MD: Electric infusion pump administration set, single-use  MD: Electric infusion pump administration set, single-use  MD: Electric infusion pump administration set, single-use  MD: Electric infusion pump administration set, single-use | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_26/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_26/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220819_26/documents/2) | Vk\_20220819\_26 |
| 23.08.2022 | Merit Medical Systems, Inc. | CorVocet Biopsy System  Model: See FSN  Lot: See FSN | MD: Soft-tissue biopsy procedure kit, non-medicated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_01/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_01/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220818_01/documents/2) | Vk\_20220818\_01 |
| 16.08.2022  (Updated 23.08.2022) | Biomedical Data Solutions Limited | Ortho Connect  Model: 3.0; 6904413; 6904414; 6904415; 6913355; 6904410; 6904411; 6904412; 6993333; 6993332 | IVD: Laboratory instrument/analyser application software IVD | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220810_15/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220810_15/documents/1) | Vk\_20220810\_15 |
| 22.08.2022 | FUJIFILM medwork GmbH | CrossSnare  Model: POL1-X1-15-23-220-OL, POL1-X1-10-23-220-OL; 502308 and 502309  Lot: 22252483, 22252574, 22252721 | MD: Snare, endoscopic | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_01/documents/0)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_01/documents/1)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_01/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_01/documents/3) | Vk\_20220805\_01 |
| 28.06.2022  (Updated 22.08.2022) | Medtronic Inc. | Cobalt XT  Model: DVPA2D1, DVPA2D4, DDPA2D1, DDPA2D4, DTPA2D4, DTPA2D1, DTPA2QQ, DTPA2Q1  S/N: All  Cobalt  Model: DVPB3D1, DVPB3D4, DDPB3D1, DDPB3D4, DTPB2D4, DTPB2D1, DTPB2QQ, DTPB2Q1  S/N: All  Crome  Model: DVPC3D1, DVPC3D4, DDPC3D1, DDPC3D4, DTPC2D4, DTPC2D1, DTPC2QQ, DTPC2Q1  S/N: All | AIMD: Dual-chamber implantable defibrillator  AIMD: Cardiac resynchronization therapy implantable defibrillator  AIMD: Cardiac resynchronization therapy implantable defibrillator | [DE-1-Notification](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/0)  [DE-1-Retrieval](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/1)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/2)  [FR-1-Notification](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/3)  [FR-1-Retrieval](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/4)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/5)  [IT-1-Notification](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/6)  [IT-1-Retrieval](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/7)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/8)  [EN-1-Notification](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/9)  [EN-1-Retrieval](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/10)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220624_01/documents/11) | Vk\_20220624\_01 |
| 25.03.2022  (Updated 22.08.2022) | Instrumentation Laboratory Co. | ACL TOP  Model: 00000280060, 00000280065, 00000280040, 00000280045, 00000280097  S/N: all | IVD: Coagulation analyser IVD, laboratory, automated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220318_05/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220318_05/documents/1) | Vk\_20220318\_05 |
| 02.08.2022  (Updated 19.08.2022) | DiaSys Diagnostic Systems GmbH | LDL-c direct FS  Model: 1 4131 99 10 921 | IVD: Low Density Lipoprotein Cholesterol including sd-LDL | [DE-1 - Distributor](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_20/documents/0)  [DE-1 - End customers](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_20/documents/1)  [EN-1 - Distributor](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_20/documents/2) | Vk\_20220729\_20 |
| 18.08.2022 | bioMérieux SA | VIDAS TB-IGRA  Model: 423111  Lot: 1008446570, 1008800300, 1008800310, 1008454760, 1008779880, 1008949330, 1009196920, 1009233340, 1009376590, 1009376580, 1009371190  S/N: N/A  SW-Version: N/A | IVD: Interferon gamma release IVD, kit, enzyme immunoassay (EIA) | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_15/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_15/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_15/documents/2) | Vk\_20220812\_15 |
| 16.08.2022  (Updated 17.08.2022) | Nutricia Medical Devices BV | Flocare Infinity Enteral feeding pump  Model: II; 35676, 35677  S/N: All  SW-Version: All | MD: Enteral feeding pump | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_08/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_08/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_08/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_08/documents/3) | Vk\_20220815\_08 |
| 17.08.2022 | Technomed Europe | Disposable Subdermal Needle Electrode, Pt/Ir  Model: TE/S46-638; TE/S46-638/01  Lot: 046241, 044220, 045077, 045443, 045831, 046574, 047126, 047843, 048428, 049285, 050426, 051402, 052709 | MD: Subdermal needle electrode | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_13/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_13/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_13/documents/2) | Vk\_20220805\_13 |
| 16.08.2022 | Löwenstein Medical Technology GmbH + Co. KG | LUISA  S/N: 50013752 - 50017318, and all devices updated by customers  SW-Version: 1.5.0030 | MD: Neonatal/adult intensive-care ventilator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_20/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220815_20/documents/1) | Vk\_20220815\_20 |
| 16.08.2022 | Datex-Ohmeda Inc. | field replacement batteries for Avance CS2, Avance CS2 Pro, Avance, Amingo, Aespire View anesthesia devices  Model: distributed on or after April 1, 2019  Avance CS2  Model: manufactured on or after April 1, 2019  Avance CS2 Pro  Model: manufactured on or after April 1, 2019 | MD: Anaesthesia workstation, general-purpose  MD: Anaesthesia workstation, general-purpose  MD: Anaesthesia workstation, general-purpose | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_01/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_01/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_01/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220812_01/documents/3) | Vk\_20220812\_01 |
| 16.08.2022 | Siemens Healthcare GmbH | Artis Q / Q.zen / pheno / icono  S/N: Artis Q / Q.zen / pheno / icono systems in combination with a specific lot of X-ray tubes | MD: Stationary angiographic x-ray system, digital | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220811_10/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220811_10/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220811_10/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220811_10/documents/3) | Vk\_20220811\_10 |
| 16.08.2022 | Drägerwerk AG & Co. KGaA | GCS 1200 Control  Model: G42156  Lot: see FSN | MD: Medical Gas/Vacuum Systems | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220810_14/documents/0) | Vk\_20220810\_14 |
| 16.08.2022 | BECTON DICKINSON INFUSION THERAPY AB | BD Venflon Pro Safety I.V. Cannula  Model: 393222, 393224, 393226, 393227, 393228, 393229, 393230, 393282  Lot: See FSN | MD: Peripheral intravenous cannula | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220518_02/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220518_02/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220518_02/documents/2) | Vk\_20220518\_02 |
| 21.09.2021  (Updated 12.08.2022) | Exactech Inc. | Exactech Knee and Ankle UHMWPE inserts  Model: See FSN  S/N: See FSN | MD: Logic CRC Insert; Logic CR Insert; Logic PS Tibia, Modinsert; Ankle Prim Mobile Liner | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/1)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/2)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/3)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/4)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/5)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/6)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20210906_17/documents/7) | Vk\_20210906\_17 |
| 10.08.2022 | Cordis Cashel | Cordis S.M.A.R.T. Flex Vascular Stent System  Model: Refer to Table 1 in FSN letter.  Lot: Refer to Table 1 in FSN letter. | MD: Peripheral artery stent, bare-metal | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_09/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_09/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_09/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_09/documents/3) | Vk\_20220729\_09 |
| 09.08.2022 | Beckman Coulter Ireland, Inc. | iChem VELOCITY Urine Chemistry Strips  Model: 800-7204  Lot: 7204612M | IVD: Urine rapid test device, multiple-constituent | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_18/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_18/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_18/documents/2) | Vk\_20220805\_18 |
| 09.08.2022 | Intuitive Surgical, Inc | da Vinci EndoWrist Clip Appliers  Model: 420230, 420327, 420003, 470230, 470327, 470401  Lot: All | MD: Robotic surgical ligation clip applier | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_12/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_12/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_12/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_12/documents/3) | Vk\_20220805\_12 |
| 09.08.2022 | IMMUCOR Medizinische Diagnostik GmbH | Automated immuClone Anti-K (Kell) IgM  Model: 0066088  Lot: 922040 (exp. Date 2022-11-30), 922041 (exp. Date 2023-04-30), 922042 (exp. Date 2023-10-31), 922043 (exp. Date 2024-04-30) | IVD: Anti-K (KEL001) red blood cell grouping IVD, antibody | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_03/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_03/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_03/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220805_03/documents/3) | Vk\_20220805\_03 |
| 09.08.2022 | GE Medical Systems Information Technologies, Inc. | Carescape Central Station | MD: Centralized patient monitor | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_11/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_11/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_11/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220804_11/documents/3) | Vk\_20220804\_11 |
| 12.07.2022  (Updated 09.08.2022) | Smiths Medical ASD Inc | H-2 Level 1 - Pressure Chamber  Model: 7204012, 7204016, 7204017, 7204018, 7204019, 7204020, 7204030, 7204034, 7204036, 7204064, 7204065, 7204068, 7204071, 7204074, CON-7204012, H-2JP, 7802722-DE, 7802722-EN, 7203019, 7203020  Lot: 44000173 to 44007145 20030142, 20040790, 20051157, 20051158, S10001740, S10001741, S10002495, S10002589, S10006978, S10007279, S10008826, S109A02601, S109A03349, S109A03352, S109A03404, S109A05072, S109A06524, S109A06731 | MD: Intravenous pressure infusor, automated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/1)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/2)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/3)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/4)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/5)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/6)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_13/documents/7) | Vk\_20220707\_13 |
| 02.08.2022  (Updated 08.08.2022) | Ortho-Clinical Diagnostics Inc. Rochester | VITROS XT7600  Model: 6844461  SW-Version: Version 3.7.2 and below  VITROS XT3400  Model: 6844458  SW-Version: Version 3.7.2 and below | IVD: Multiple clinical chemistry analyser IVD, laboratory, automated  IVD: Dry clinical chemistry analyser IVD, automated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220726_13/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220726_13/documents/1) | Vk\_20220726\_13 |
| 08.08.2022 | Olympus Medical Systems Corp. | OLYMPUS DUODENOVIDEOSCOPE  Model: TJF-Q170V & TJF-Q190V & TJF-Q290V Duodenovideoscopes; N5992960, N5992950, N5425051, N5993260, N5993250, N6000360  S/N: All | MD: Flexible video duodenoscope, reusable | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211214_01/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211214_01/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211214_01/documents/2) | Vk\_20211214\_01 |
| 08.08.2022 | Datex-Ohmeda Inc. | Carestation 750, Carestation 750c | MD: Anaesthesia workstation, general-purpose | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211210_16/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211210_16/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211210_16/documents/2) | Vk\_20211210\_16 |
| 08.08.2022 | Philips Medical Systems Nederland B.V | BV Pulsera und BV Endura (Chirurgie Bildverstärker)  Model: BV Endura - 718075 , BV Pulsera - 718095  S/N: See FSN  Veradius  Model: Veradius Unity - 718132  S/N: See FSN  BV Vectra  Model: 718400  S/N: See FSN | MD: Stationary general-purpose fluoroscopic x-ray system, analogue  MD: C-arm, diagnostic x-ray unit, mobile  MD: Mobile general-purpose fluoroscopic x-ray system, analogue | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211208_28/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211208_28/documents/1)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211208_28/documents/2)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211208_28/documents/3)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211208_28/documents/4)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211208_28/documents/5) | Vk\_20211208\_28 |
| 05.08.2022 | Barco | Barco  Model: MNA-240 ENC DP, MNA-240 ENC DP MQ, MNA-240 ENC DP OL, MNA-240 ENC DP KS | MD: Image display monitor, colour | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/0)  [DE-1-Karl Storz](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/1)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/2)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/3)  [FR-1-Karl Storz](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/4)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/5)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/6)  [IT-1-Karl Storz](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/7)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_21/documents/8) | Vk\_20220725\_21 |
| 15.03.2022  (Updated 04.08.2022) | DNA Genotek Inc | ORAcollect DNA  Model: OCR-100  Lot: Multiple  ORAcollect Dx/ ORAcollect RNA  Model: OCD-100; OCD-100A; ORE-100  Lot: Multiple | MD: Oral/respiratory tract specimen container IVD, additive/medium  MD: Oral/respiratory tract specimen container IVD, additive/medium | [DE-1\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/0)  [DE-2\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/1)  [FR-1\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/2)  [FR-2\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/3)  [IT-1\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/4)  [IT-2\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/5)  [EN-1\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/6)  [EN-1\_ORAcollect Dx\_RNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/7)  [EN-2\_ORAcollect DNA](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220315_06/documents/8) | Vk\_20220315\_06 |
| 03.08.2022 | Medtronic Inc. | Vanta LT Clinician Programmer Application  Model: A71200  S/N: All  SW-Version: 2.0.2455 | AIMD: Multiple active implantable device programmer | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_03/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_03/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_03/documents/2) | Vk\_20220729\_03 |
| 03.08.2022 | Medtronic Inc. | Vanta LT Clinician Programmer Application  Model: A71200  S/N: All  SW-Version: 2.0.2455 | AIMD: Multiple active implantable device programmer | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_02/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_02/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_02/documents/2) | Vk\_20220729\_02 |
| 26.07.2022  (Updated 03.08.2022) | Alere San Diego, Inc | Cholestech LDX Cassette  Model: 10-987, 10-989 , 10-990, 10-991, 99021, 14-531 | IVD: Lipid peroxide IVD, reagent | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220721_13/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220721_13/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220721_13/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220721_13/documents/3) | Vk\_20220721\_13 |
| 03.08.2022 | Metrax GmbH | PRIMEDIC HeartSave  Model: 73943100000 - 73943100367, 73944100000 - 73944100594, 73945100000- 73945100928, 73946100000 - 73946100569 | MD: Defibrillators, External, Automated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220712_13/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220712_13/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220712_13/documents/2) | Vk\_20220712\_13 |
| 02.08.2022 | DiaSys Diagnostic Systems GmbH | NEFA FS  Model: 1 5781  Lot: 31731 | IVD: Non Esterified Fatty Acids | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_21/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220729_21/documents/1) | Vk\_20220729\_21 |
| 02.08.2022 | GE Healthcare IITS USA Corporation | Centricity Universal Viewer  S/N: Software Versions, 6.0 SP9 through 6.0 SP10.4, 7.0 SP0 through SP0.0.4.9, 7.0 SP0.0.5, 7.0 SP0.1.0, 7.0 SP1, 8.0 SPB through SP0.1.1  SW-Version: Refer to field "Serial numbers) | MD: Medical image management system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220728_01/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220728_01/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220728_01/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220728_01/documents/3) | Vk\_20220728\_01 |
| 29.07.2022 | Fresenius Kabi AG | COMPOFLEX 1F 63 ml CPDA1 - PDS - V  Model: PS11150  Lot: Within shelf live  COMPOSTOP FLEX 2F PLT PROC. LEUKO RED  Model: PD51600  Lot: Within shelf live  COMPOFLEX 1F 63CPDA-1 LUER-M  Model: PS111EA  Lot: Within shelf live  CompoStop Flex 3F T&B - 7-PLT pool  Model: PT52600  Lot: Within shelf live  COMPOFLEX 1F EMPTY 600 PD-V  Model: T2131  Lot: Within shelf live | MD: Blood donor set, single-pack  MD: Blood donor set, double-pack  MD: Blood donor set, double-pack  MD: Blood donor set, triple-pack  MD: Blood donor set, single-pack | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_15/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_15/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_15/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_15/documents/3) | Vk\_20220722\_15 |
| 19.07.2022  (Updated 28.07.2022) | OCULUS Optikgeräte GmbH | Pentacam AXL  Model: 70100  S/N: Software Version 1.26r26 & 1.26r27  SW-Version: 1.26r26 & 1.26r27  Pentacam HR  Model: 70900  S/N: Software Version 1.26r26 & 1.26r27  SW-Version: 1.26r26 & 1.26r27  Pentacam AXL Wave  Model: 70020  S/N: Software Version 1.26r26 & 1.26r27  SW-Version: 1.26r26 & 1.26r27 | MD: Anterior segment analysis device  MD: Corneal topography system  MD: Corneal topography system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_20/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_20/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_20/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_20/documents/3) | Vk\_20220715\_20 |
| 27.07.2022 | MAQUET Cardiopulmonary GmbH | HLS Set Advanced 7.0  Model: 701069073; 701069083  Lot: See FSN  HLS Set Advanced 5.0  Model: 701069076  Lot: See FSN | MD: Cardiopulmonary bypass system tubing set  MD: Cardiopulmonary bypass system tubing set | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_14/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_14/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_14/documents/2) | Vk\_20220722\_14 |
| 27.07.2022 | Cook Incorporated | Roadrunner PC Hydrophilic Wire Guide  Model: see FSN  Lot: see FSN  Roadrunner UniGlide Hydrophilic Wire Guide  Model: see FSN  Lot: see FSN | MD: Peripheral vascular guidewire, manual  MD: Peripheral vascular guidewire, manual | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_09/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_09/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_09/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_09/documents/3) | Vk\_20220720\_09 |
| 21.03.2022  (Updated 27.07.2022) | Gelita Medical GmbH | GELITA-SPON RAPID3  Model: GR-010; GR-310; GR-610; GR-005; GR-007  Lot: All  GELITA-SPON Standard  Model: GS-010 DP; GS-015; GS-030; GS-060; GS-110; GS-003; GS-325; GS-004; GS-610; GS-950; GS-010 SP; GS-210; GS-310; GS-002  Lot: All  GELITA-SPON POWDER  Model: GS-265  Lot: All  GELITA ENT X-PASTE  Model: GE-2165  Lot: All  GELITA ENT X-DENSE  Model: GE-6385; GE-6311  Lot: All  GELITA ENT X-BLOD  Model: GE-8382; GE-8385  Lot: All  GELITA ENT X-PAND  Model: GE-6382  Lot: All | MD: Gelatin haemostatic agent  MD: Gelatin haemostatic agent  MD: Gelatin haemostatic agent  MD: Gelatin haemostatic agent  MD: Gelatin haemostatic agent  MD: Gelatin haemostatic agent  MD: Gelatin haemostatic agent | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/0)  [DE-2 Expansion](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/1)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/2)  [FR-2 Expansion](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/3)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/4)  [IT-2 Expansion](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/5)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/6)  [EN-3 Expansion](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_02/documents/7) | Vk\_20220314\_02 |
| 26.07.2022 | GE Medical Systems, LLC | SIGNA Premier  Model: 00840682135269, 00195278010797 | MD: Full-body MRI system, superconducting magnet | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_17/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_17/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_17/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220725_17/documents/3) | Vk\_20220725\_17 |
| 26.07.2022 | Thermo Fisher Scientific Microbiology Basingstoke | RapID NF PLUS System 20/KT  Model: R8311005  Lot: 3364798, 3364799, 3364800, 3381406, 3390383, 3442256 and 3442431 | IVD: Multiple non-glucose fermenting bacteria species culture isolate identification IVD, kit | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_05/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_05/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_05/documents/2) | Vk\_20220722\_05 |
| 26.07.2022 | Laboratoires Chemineau | BENTRIO  Model: 7649998266062  Lot: CH113 | MD: Nasal mucosa dressing, non-antimicrobial | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_28/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_28/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_28/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_28/documents/3) | Vk\_20220720\_28 |
| 26.07.2022 | Albino Dias de Andrade | Gauze dressings with X-ray contrast thread, steril  Model: 22221.1  Lot: 0053922ES  S/N: 005165 | MD: Cotton Gauzes, Folded, With X-ray Detectable Thread, Sterile | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_16/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_16/documents/1) | Vk\_20220720\_16 |
| 26.07.2022 | Siemens Healthcare Diagnostics Inc | Dimension Vista CA 15-3 Flex reagent cartridge  Model: Dimension Vista; SMN 10464344  Lot: see FSN  S/N: N/A  SW-Version: N/A | IVD: Cancer antigen 15-3 (CA15-3) IVD, kit, chemiluminescent immunoassay | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_03/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220720_03/documents/1) | Vk\_20220720\_03 |
| 22.07.2022 | Messer Schweiz AG | Kohlendioxid med RPV  Model: 103020102  Lot: see FSN  S/N: See FSN | MD: Clinical/therapeutic Applications Carbon Dioxide | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_03/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220722_03/documents/1) | Vk\_20220722\_03 |
| 22.07.2022 | Axon Biotech GmbH | Mueller-Hinton-Agar  Model: AL0901  Lot: see FSN | IVD: Other Prepared Media in Plates | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_19/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_19/documents/1)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_19/documents/2) | Vk\_20220715\_19 |
| 22.07.2022 | Intuitive Surgical, Inc | Generator, E-100  Model: 374848-09  S/N: see FSN | MD: Electrosurgical system generator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_17/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_17/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_17/documents/2) | Vk\_20220714\_17 |
| 21.07.2022 | Haemonetics S.A. | TEG 6s Hemostasis Analyzer  Model: 07-690  Lot: N/A  S/N: N/A  SW-Version: 1.7.2 | IVD: Coagulation analyser IVD, laboratory, automated | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_03/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_03/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_03/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220715_03/documents/3) | Vk\_20220715\_03 |
| 12.07.2022  (Updated 21.07.2022) | KERI MEDICAL SA | KeriLock(R) - Screwed suture anchor kits 2.0 and 4.0  Model: 2.0 and 4.0; 500-B20001 and 500-B20002  Lot: KeriLock 2.0 : 20-0627 - 20-0628 - 20-0629, KeriLock 4.0 : 20-0631 | MD: Tendon/ligament bone anchor, non-bioabsorbable | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_10/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_10/documents/1) | Vk\_20220707\_10 |
| 20.07.2022 | GE Hangwei Medical Systems Co., Ltd | CT, PET, or NM table  Model: see FSN  Lot: see FSN | MD: X-Ray System, Diagnostic, Computed Tomography | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_15/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_15/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_15/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_15/documents/3) | Vk\_20220713\_15 |
| 20.07.2022 | Datex-Ohmeda Inc. | Carestation 750, Carestation 750c  Lot: UNK | MD: Anaesthesia workstation, general-purpose | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_09/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_09/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_09/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_09/documents/3) | Vk\_20220713\_09 |
| 20.07.2022 | bioMérieux SA | VIDAS FT4  Model: 30459  Lot: 1009142040, 1009140070, 1009168620, 1009384040, 1009434270  S/N: N/A  SW-Version: N/A | IVD: Free thyroxine (FT4) IVD, kit, enzyme immunoassay (EIA) | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_06/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_06/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220713_06/documents/2) | Vk\_20220713\_06 |
| 20.07.2022 | Cardiac Pacemaker Inc | EMBLEM MRI S-ICD  Model: Model A219  Lot: N/A  S/N: To determine if a device is included in this Field Safety Notice, enter the model/serial number at www.BostonScientific.com/lookup, or review the customer list provided.  SW-Version: Model 3877 v1.03 and Model 2877 v4.09  Emblem S-ICD  Model: Model A209  Lot: N/A  S/N: To determine if a device is included in this Field Safety Notice, enter the model/serial number at www.BostonScientific.com/ lookup, or review the customer list provided. | MD: Subcutaneous Implantable Defibrillators  AIMD: Single-chamber implantable defibrillator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_04/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_04/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_04/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_04/documents/3) | Vk\_20220708\_04 |
| 13.07.2022  (Updated 20.07.2022) | Smith & Nephew, Inc. | Werewolf Flow 90° Wand  Model: 72290038  Lot: 2086510, 2087447, 2087448, 2087450, 2087451, 2087452, , 2087449, 2087969, 2087970 and 2087986 | MD: Endoscopic electrosurgical handpiece/electrode, bipolar, single-use | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220706_08/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220706_08/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220706_08/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220706_08/documents/3) | Vk\_20220706\_08 |
| 19.07.2022 | ev3 | EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEM STANDARD  Model: all  Lot: all | MD: Peripheral artery stent, bare-metal | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_26/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_26/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_26/documents/2) | Vk\_20220714\_26 |
| 19.07.2022 | Medicina Ltd | ENFit Enteral Syringe  Model: LHE01LD, LHE25LD, LHE05, OT005, OT01, OT25, OT05, OTH01, OTH25, OTH05; LHE01LD, LHE25LD, LHE05, OT005, OT01, OT25, OT05, OTH01, OTH25, OTH05 | MD: ENFit oral/enteral syringe, single-use; ENFit oral/enteral syringe, reusable | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_25/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_25/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220714_25/documents/2) | Vk\_20220714\_25 |
| 15.07.2022  (Updated 19.07.2022) | Siemens Healthcare GmbH | Axiom Sensis  Model: See FSN  AXIOM Sensis XP  Model: See FSN  AXIOM Sensis Lite  Model: See FSN  AXIOM Sensis Vibe Combo  Model: See FSN | MD: Cardiac catheterization laboratory computer  MD: Cardiac catheterization laboratory computer  MD: Cardiac catheterization laboratory computer  MD: Cardiac catheterization laboratory computer | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_22/documents/0)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_22/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_22/documents/2) | Vk\_20220711\_22 |
| 29.06.2022  (Updated 19.07.2022) | Maquet Critical Care AB | SERVO-air  Model: 6682000  SW-Version: N/A | MD: Neonatal/adult intensive-care ventilator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_04/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_04/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_04/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_04/documents/3) | Vk\_20220628\_04 |
| 29.06.2022  (Updated 19.07.2022) | Maquet Critical Care AB | SERVO  Model: 6694800 Servo-u; 6688600 Servo-n; 6888800 Servo-u MR; 6682000 Servo-air | MD: General-purpose intensive-care ventilator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/1)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/2)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/3)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/4)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/5)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220623_10/documents/6) | Vk\_20220623\_10 |
| 17.05.2022  (Updated 19.07.2022) | BECTON DICKINSON INFUSION THERAPY AB | BD Connecta Stopcock Without Extension Tube  Model: 394600; 394601; 394602  Lot: See FSN  BD Nexiva Closed IV Catheter System  Model: 383682; 383687  Lot: See FSN | MD: Intravenous line stopcock  MD: Intravenous line stopcock | [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220512_09/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220512_09/documents/1)  [FR-2 Expansion](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220512_09/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220512_09/documents/3)  [EN-2 Expansion](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220512_09/documents/4) | Vk\_20220512\_09 |
| 15.07.2022 | Renishaw Mayfield SARL | Neuroinpsire  SW-Version: All software versions | MD: Image segmentation application software | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_07/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_07/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_07/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220707_07/documents/3) | Vk\_20220707\_07 |
| 14.07.2022 | DePuy Ireland | ATTUNE Measured Sizing & Rotation Guide Instrument  Model: 254400525  Lot: AB4536235, AB4733296, AB4841493, AB4810808, AB4841495, AB4904565, AB4967214, AB5004557, AB5034303  S/N: 10603295434061 | MD: Orthopaedic prosthesis implantation instrument, reusable | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_25/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_25/documents/1) | Vk\_20220629\_25 |
| 13.07.2022 | Siemens Healthcare Diagnostics Inc | Atellica CH Iron\_2  Model: 11097601  Lot: All lots  S/N: N/A  SW-Version: N/A | IVD: Iron IVD, kit, spectrophotometry | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_05/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_05/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_05/documents/2) | Vk\_20220701\_05 |
| 07.07.2022  (Updated 13.07.2022) | Mallinckrodt Manufacturing LLC | INOmax DSIR  S/N: All | MD: Nitric oxide delivery unit, system-based | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_01/documents/0)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_01/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_01/documents/2) | Vk\_20220629\_01 |
| 12.07.2022 | GE Healthcare Finland Oy | Centricity High Acuity Critical Care  SW-Version: CHA Critical Care and Anesthesia 5.2 to 5.8 | MD: Patient health record information system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_26/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_26/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_26/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220711_26/documents/3) | Vk\_20220711\_26 |
| 12.07.2022 | Cardiac Pacemaker Inc | Zoom Latitude Programmer  Model: 3120  S/N: To determine if a device is included in this Field Safety Notice, enter the model/serial number at www.BostonScientific.com/lookup  SW-Version: Model 2868 | AIMD: Cardiac pulse generator programmer | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_02/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_02/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_02/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220708_02/documents/3) | Vk\_20220708\_02 |
| 05.07.2022  (Updated 12.07.2022) | OphthalmoPro GmbH | Optyluron NHS | MD: Shields, Mechanical, Eye | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220705_09/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220705_09/documents/1) | Vk\_20220705\_09 |
| 12.07.2022 | Stryker Instruments-a division of Stryker Corp | 2.3MM TAPERED ROUTER  Model: 5820071023  Lot: 22011017 , 21330017 , 20216017 , 20140017, 20139027 | MD: Cranial bur, single-use | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_04/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_04/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_04/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220701_04/documents/3) | Vk\_20220701\_04 |
| 14.06.2022  (Updated 12.07.2022) | Covidien LLC | PALINDROME  Lot: 17144xxxxx through 22038xxxxx.  S/N: see FSN  SW-Version: N/A | MD: Double-lumen haemodialysis catheter, implantable | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220608_15/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220608_15/documents/1)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220608_15/documents/2)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220608_15/documents/3)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220608_15/documents/4) | Vk\_20220608\_15 |
| 22.03.2022  (Updated 12.07.2022) | Respironics California, LLC | V60 Ventilator  V60 Plus Ventilator  V680 Ventilator | MD: Portable electric ventilator  MD: Portable electric ventilator  MD: General-purpose intensive-care ventilator | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/0)  [DE-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/1)  [DE-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/2)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/3)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/4)  [FR-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/5)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/6)  [IT-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/7)  [IT-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/8)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/9)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/10)  [EN-3](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220314_28/documents/11) | Vk\_20220314\_28 |
| 05.07.2022  (Updated 11.07.2022) | HeartWare Inc. | HeartWare Ventricular Assist System  Model: 1650DE  S/N: All  SW-Version: N/A | AIMD: Implantable ventricular circulatory assist system | [DE-1A](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_24/documents/0)  [DE-1B](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_24/documents/1)  [EN-1A](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_24/documents/2)  [EN-1B](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_24/documents/3) | Vk\_20220629\_24 |
| 01.12.2021  (Updated 08.07.2022) | Qiagen GmbH | QIAcube Connect MDx  Model: 9003070  Lot: n/a  S/N: All  SW-Version: n/a | IVD: Nucleic Acid Testing Extraction Instruments | [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211126_06/documents/0)  [FR-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211126_06/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211126_06/documents/2)  [EN-2](https://fsca.swissmedic.ch/mep/api/publications/Vk_20211126_06/documents/3) | Vk\_20211126\_06 |
| 07.07.2022 | Hegewald Medizinprodukte GmbH | MIB Infusionsmischbeutel  Model: 1021700, 1021720, 1021705  Lot: BMH70012, BLH70011, BMH72004, CCH70502 | MD: Medical Bags | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220629_16/documents/0) | Vk\_20220629\_16 |
| 08.06.2022  (Updated 07.07.2022) | 3M ESPE Dental Products | 3M ESPE Filtek Supreme Flowable Restorative Caps.  Model: 6033A1, 6033A2, 6033A3, 6033A3.5, 6033B1, 6033B2, 6033C2, 6033OA3  Lot: NF15043, NE98405, NF05501, NF10756, NF11091, NF10945, NE99885, NE88238, NE87132, NE87133 | MD: Dental composite resin | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220601_15/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220601_15/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220601_15/documents/2) | Vk\_20220601\_15 |
| 06.07.2022 | GE Healthcare IITS USA Corporation | Centricity PACS  SW-Version: Centricity PACS 7.0 SP0.0.4.7 | MD: Radiology picture archiving and communication system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_25/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_25/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_25/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_25/documents/3) | Vk\_20220704\_25 |
| 06.07.2022 | GE Healthcare IITS USA Corporation | Centricity Universal Viewer Zero Footprint Client  SW-Version: Versions 6.0 SP6 through 6.0 SP11.4 | MD: Medical image management system | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_06/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_06/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_06/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220628_06/documents/3) | Vk\_20220628\_06 |
| 05.07.2022 | Getinge Disinfection AB | ED-FLOW, ED-FLOW SD  Model: ED-FLOW, ED-FLOW SD  S/N: All ED-FLOW AER-models manufactured since start 2010 until 2022-05-05 | MD: Endoscope washer/disinfector | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_27/documents/0)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_27/documents/1) | Vk\_20220704\_27 |
| 05.07.2022 | Dynex Technologies | Agility Automated ELISA System  Model: 67800 (Software)  SW-Version: 1.4.3 | IVD: Multiple clinical chemistry analyser IVD, laboratory, automated | [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_04/documents/0) | Vk\_20220704\_04 |
| 05.07.2022 | Biomerieux | NucliSENS easyMAG Magnetic Silica  Model: 280133  Lot: See FSN | IVD: Nucleic acid extraction/isolation kit IVD | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_02/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_02/documents/1)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220704_02/documents/2) | Vk\_20220704\_02 |
| 02.06.2022  (Updated 01.07.2022) | Waldemar Link GmbH & Co. KG | Endo-Model-M  Model: tibial components, see FSN  Lot: All after manufacturing date 2021-08 until manufacturing date 2022-05  Endo-Model SL  Model: tibial components, see FSN  Lot: All after manufacturing date 2021-08 until manufacturing date 2022-05 | MD: Uncoated knee tibia/insert prosthesis  MD: Rotating hinged total knee prosthesis | [DE-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220523_16/documents/0)  [FR-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220523_16/documents/1)  [IT-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220523_16/documents/2)  [EN-1](https://fsca.swissmedic.ch/mep/api/publications/Vk_20220523_16/documents/3) | Vk\_20220523\_16 |