**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 spectroscopyIVD: 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-adjustableMD: 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 - OtherIVD: Multi-modality clinical specimen analysis system IVDIVD: Integrated / Modular Chemistry / Immunochemistry Instruments - OtherIVD: Automated Immunochemistry Analysers - Moderate To High Routine (throughput > 250 And <= 700 Test/h)IVD: Chemiluminescent immunoassay analyser IVDIVD: Integrated / Modular Chemistry / Immunochemistry Instruments - OtherIVD: 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 catheterMD: 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 spectrophotometryIVD: 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 microscopeMD: Operative MicroscopesMD: Neurosurgical microscopeMD: 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, reusableMD: CPAP/BPAP nasal mask, reusableMD: CPAP/BPAP face mask, reusableMD: CPAP/BPAP nasal mask, reusableMD: 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-purposeMD: Anaesthesia workstation, general-purposeMD: 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 SetsMD: 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 immunoassayIVD: 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-purposeMD: Anaesthesia workstation, general-purposeMD: 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, manualMD: Peripheral vascular guidewire, manualMD: Peripheral vascular guidewire, manualMD: Peripheral vascular guidewire, manualMD: Low-pressure tubing connector, single-use, sterileMD: 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 IVDIVD: Differential/selective agar culture medium IVDIVD: 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-useMD: Electric infusion pump administration set, single-useMD: Electric infusion pump administration set, single-useMD: 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 defibrillatorAIMD: Cardiac resynchronization therapy implantable defibrillatorAIMD: 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-purposeMD: Anaesthesia workstation, general-purposeMD: 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, automatedIVD: 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, analogueMD: C-arm, diagnostic x-ray unit, mobileMD: 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/mediumMD: 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-packMD: Blood donor set, double-packMD: Blood donor set, double-packMD: Blood donor set, triple-packMD: 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 deviceMD: Corneal topography systemMD: 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 setMD: 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, manualMD: 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 agentMD: Gelatin haemostatic agentMD: Gelatin haemostatic agentMD: Gelatin haemostatic agentMD: Gelatin haemostatic agentMD: Gelatin haemostatic agentMD: 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 DefibrillatorsAIMD: 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 computerMD: Cardiac catheterization laboratory computerMD: Cardiac catheterization laboratory computerMD: 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 stopcockMD: 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 ventilatorMD: Portable electric ventilatorMD: 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 prosthesisMD: 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  |