

Field Safety Notice Summary Sheet

Outstanding Field Safety Corrective Actions

Field safety notices included in this summary sheet since the last issuance of this document are highlighted in grey

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
CRN00D P8X	Septodont Parcan N NaOCL 3% Solution	Inter-med, Inc.	Advice has been provided regarding the use of the device	June 2023	Manufacturer's FSN
V53719	Studio Reformer	Balanced Body, Inc.	Advice has been provided regarding the use of the device	January 2023	Manufacturer's FSN
V51339	Lepu Medical SARS-CoV-2 Antigen Rapid Test Kits for Self-testing	Beijing Lepu Medical Technology Co., Ltd.	Advice regarding the use of the device	May 2022	Manufacturer's FSN
V50807	Arjo Sara Plus lift	ArjoHuntleigh	Advice has been provided regarding a device modification	March 2022	Manufacturer's FSN
V47222	EcoGel 200 Ultrasound Gel	Eco-Med Pharmaceuticals, Inc.	Advice has been provided regarding a device removal	December 2021	Manufacturer's FSN
V48119	Infinity™ Ammonia Liquid Stable Reagent & Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	Thermo Fisher Scientific Inc.	Advice regarding the use of the device	November 2021	Manufacturer's FSN 1 Manufacturer's FSN 2
V47420	HE™ Synthetic Standard SARS-CoV-2 Process Control (swab)	Microbiologics, Inc.	Advice regarding the use of the device.	September 2021	Manufacturer's FSN
V47440	Celect & Gunther IVC Filter	Cook Medical	Updates made to instructions for use	September 2021	Manufacturer's FSN
V47427	HE™ Synthetic Standard SARS-CoV-2 Process Control (pellet)	Microbiologics, Inc.	Advice regarding the use of the device.	September 2021	Manufacturer's FSN

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V46496	Biotrue® contact lens solution, ReNu® MPS Multi-purpose solution sensitive eyes, ReNu® MultiPlus contact lens solution, Boston® cleaner, Boston® conditioning solution, Boston® Simplus Multi-Action contact lens solution, Sensitive Eyes® cleaner, Boston® conditioning solution, Boston® Simplus Multi-Action contact lens solution, Sensitive Eyes® contact lens solution, EasySept® contact lens solution, Ophtaxia® eye wash solution, Sensitive Eyes® eye lubricant solution	Bausch and Lomb	Advice has been provided regarding a device removal	May 2021	Manufacturer's FSN
V46369	Nimbus Mattress	ArjoHuntleigh	Advice regarding a device modification	April 2021	Manufacturer's FSN
V46116	COLLEAGUE SINGLE CHANNEL, COLLEAGUE SINGLE CHANNEL CXE, COLLEAGUE SINGLE CHANNEL MONO, COLLEAGUE TRIPLE CHANNEL, COLLEAGUE TRIPLE CHANNEL CXE, COLLEAGUE TRIPLE CHANNEL MONO	Baxter	Advice has been provided regarding changes/updates made to instructions for use	March 2021	Manufacturer's FSN
V45959	Maxi Sky 1000 & V10 Ceiling Lifts	ArjoHuntleigh	Advice regarding the use of the device	March 2021	Manufacturer's FSN
V46134	MyWay Walker	James Leckey Design Ltd	Advice regarding a device modification	March 2021	Manufacturer's FSN
V46193	COLLEAGUE PUMP, EVO IQ LVP, EVO IQ SYR	Baxter	Advice regarding the use of the device.	March 2021	Manufacturer's FSN

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V45619	Real 9000, 6100 and 2000 series Wheelchairs	Mercado Medic AB	Advice regarding changes/updates made to instructions for use	February 2021	Manufacturer's FSN
V45402	BEMER Classic and Pro therapy systems	BEMER International AG	Advice has been provided regarding changes/updates made to instructions for use	December 2020	Manufacturer's FSN
V45365	CareLink™ Personal v14.1a (MMT-7333) using CareLink™ uploader (ACC-7350) CareLink™ system v3.1a (MMT-7350) using CareLink™ uploader (ACC-7350)	Medtronic	Advice has been provided regarding a software upgrade	December 2020	Manufacturer's FSN
V44927	Flat Dynamic Positioning System	ArjoHuntleigh	Advice regarding the use of the device	October 2020	Manufacturer's FSN
V43286	Real 9000 Plus Wheelchairs	Mercado Medic AB	Advice regarding the use of the device	March 2020	Manufacturer's FSN
V43275	Afinion 2 and Alere Afinion AS100 Analyzers	Abbott Diagnostics Technologies AS	Advice regarding a device modification	March 2020	Manufacturer's FSN
V42994	MyWay Harness	Leckey	Advice regarding a device modification	February 2020	Manufacturer's FSN
V42062	Remel E. coli Polyvalent Agglutinating Sera	Remel Europe Ltd	Advice has been provided regarding a device removal	November 2019	Manufacturer's FSN
V42649	NIPPY 3+, Junior +, ST+ and S+	BREAS	Advice has been provided regarding the use of the device	October 2019	Manufacturer's FSN
V41836	Firefly Splashy, Firefly GoTo Seat	James Leckey Design Limited	Advice regarding a device modification	October 2019	Manufacturer's FSN
V40485	Neutrogena Light Therapy Acne Mask and Refill Activator	Johnson and Johnson GmbH	Advice has been provided regarding a device removal	July 2019	Manufacturer's Customers FSN Manufacturer's Retail Pharmacy FSN
V40660	Calibration Serum Level 3	Randox Laboratories Ltd	Advice has been provided regarding the use of the device	July 2019	Manufacturer's FSN

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V40326	RX Daytona +, RX Imola	Randox Laboratories Limited	Advice has been provided regarding use of the device	June 2019	Manufacturer's FSN
V40239	HeartStart MRx (M3539A AC Power Module)	Philips Medical Systems	Advice has been provided regarding use of the device	May 2019	Manufacturer's FSN
V40173	Guardian Connect Application	Medtronic	Advice has been provided regarding a software upgrade	May 2019	Manufacturer's FSN
V39337	Leica CM1950, Leica CM1860/UV, Leica CM1520, Leica CM3050 S, Leica CM1850 UV, Leica CM1850, Leica CM1510 S, Leica CM110	Leica Biosystems	Advice regarding changes/updates made to instructions for use	March 2019	Manufacturer's FSN
V38869	HAMILTON-G5/S1 ventilator unit	Hamilton Medical AG	Advice has been provided regarding a software upgrade	February 2019	Manufacturer's FSN
V38311	Autostainer Slide Racks	Dako North America Inc	Advice has been provided regarding changes/updates made to instructions for use	December 2018	Manufacturer's FSN
V37811	HemoTrol Normal (Level 2), HemoTrol High (Level 3), CueSee® tHb Level 2 & Level 3	Eurotrol B.V	Advice has been provided regarding a device removal	October 2018	Manufacturer's FSN
V36759	Jumper AngelSounds JPD-100S4	Jumper Medical Equipment Co. Ltd.	Advice has been provided regarding changes/updates made to instructions for use	August 2018	Manufacturer's FSN
V36364	Guardian™ Connect Mobile App	Medtronic	Advice has been provided regarding a software upgrade	July 2018	Manufacturer's FSN1 Manufacturer's FSN2 Manufacturer's FSN3
V36384	ILAB AKI 2.1 Build 5	DXC Technology	Advice has been provided regarding use of the device	July 2018	Manufacturer's FSN
V36189	Alaris™/ Asena™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump	BD Switzerland Sàrl	Advice has been provided regarding a device modification	June 2018	Manufacturer's FSN
V35346	T34 Ambulatory Syringe Pump	Caesare Medical Electronics Limited	Advice regarding the use of the device	March 2018	Manufacturer's FSN

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V35048	Philips HeartStart FRx AED, Philips HS1 (Onsite) AED, Philips HS1 (Home) AED	Philips Medical Systems	Advice has been provided regarding use of the device	March 2018	Manufacturer's FSN
V34743	HA200 Unipump - Opal, Opal Plus, Salisbury and Prime Overlay Mattresses and HH20 Active Seat System	Harvest Healthcare Ltd	Advice has been provided regarding changes/updates made to instructions for use	February 2018	Manufacturer's FSN
V38760	Commander Delivery System	Edwards Lifesciences	Advice has been provided regarding use of the device	February 2018	Manufacturer's FSN
V34482	Philips Ear Thermometer (DL8740) and Philips AVENT Smart Ear Thermometer (SCH740)	Philips Consumer Lifestyle B.V.	Advice has been provided regarding use of the device	January 2018	Manufacturer's FSN
V33494	Alaris™ / Asena™ GS, GH, CC, TIVA, PK, Syringe Pump	Carefusion	Advice has been provided regarding the use of the device	October 2017	Manufacturer's FSN
V33605	Entral Enfit Nasogastric (NG) Feeding Tubes	Maxter	Advice has been provided regarding a device removal	October 2017	Manufacturer's FSN
V33836	SmartBase	Autochair Ltd	Advice has been provided regarding a device modification	October 2017	Manufacturer's FSN
V33345	MAQUET HLX 2004-5 DF, HLX 3004-5 DF and XTEN DF	MAQUET SAS	Advice has been provided regarding a device modification	September 2017	Manufacturer's FSN
V32407	NovoPen® Echo® and NovoPen® 5	Novo Nordisk	Advice has been provided regarding a device removal	July 2017	Manufacturer's FSN
V32458	ATAR extension cables	Oscor Inc.	Advice has been provided regarding a device removal	July 2017	Manufacturer's FSN
V32409	OXFORD - DIPPER	Joerns Healthcare Limited	Advice regarding the use of the device	July 2017	Manufacturer's FSN
V32571	Rebound Foot Up	Ossur	Advice has been provided regarding a device removal	July 2017	Manufacturer's FSN

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V32113	BVM Manual Resuscitation Systems	Intersurgical UAB	Advice has been provided regarding changes/updates made to instructions for use	June 2017	Manufacturer's FSN
V31964	Ixos P4 Wave	KLS Martin	Advice has been provided regarding a device removal	May 2017	Manufacturer's FSN
V30582	BD Plastipak™ Syringe, Catheter tip with Luer slip adaptor	Becton Dickinson	Advice has been provided regarding a device removal	January 2017	Manufacturer's FSN
V30597	CORFLO* PEG Y Adapter with ENFit® Connectors	CORPAK Medsystems	Advice regarding the use of the device	January 2017	Manufacturer's FSN
V30349	GlucofactsDeluxe	Ascensia Diabetes Care	Advice has been provided regarding a software upgrade	December 2016	Manufacturer's FSN
V30170	i.Laboratory 5.8.1002	CSC	Advice has been provided regarding the use of the device	December 2016	Manufacturer's FSN
V30050	BD Plastipak / Oral Syringes	Becton, Dickinson and Company Limited	Advice has been provided regarding changes/updates made to instructions for use	November 2016	Manufacturer's FSN
V30698	Unomedical a/s Infusion sets Comfort™, Comfort™ short	Unomedical	Advice has been provided regarding the use of the device	November 2016	Manufacturer's FSN 1 Manufacturer's FSN 2
V29210	Combur-Test/Chemstrip/Choiceline	Roche	Advice has been provided regarding changes/updates made to instructions for use	September 2016	Manufacturer's FSN
V29583	Laerdal Suction Unit	Laerdal Medical	Advice has been provided regarding a device modification	September 2016	Manufacturer's FSN 1 Manufacturer's FSN 2
V29189	Klerpack BD Syringe Multi-Pack	Ecolab Ltd.	Advice has been provided regarding a device removal	September 2016	Manufacturer's FSN 1 Manufacturer's FSN 2 Manufacturer's FSN 3
V29152	MS3 Connex Spot Classic Mobile Stand & Power Supply	Welch Allyn	Advice has been provided regarding a device modification	September 2016	Manufacturer's FSN
V29397	UK (Type G) detachable power plugs for certain Medela breast pumps	Medela	Advice has been provided regarding a device removal	September 2016	Manufacturer's FSN

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V28955	NIO Intraosseous Device	WaisMed	Advice has been provided regarding a device removal	August 2016	Manufacturer's FSN
V29117	Birdie Lifter	Invacare	Advice has been provided regarding the use of the device	August 2016	Manufacturer's FSN
V29086	Comfort Shield Barrier Cream Cloths	Sage Products LLC	Advice has been provided regarding a device removal	August 2016	Manufacturer's FSN
V29171	Varilite Cushion	BES Corporate	Advice has been provided regarding a device modification	August 2016	Manufacturer's FSN
V28211	TAPERLOC Hip Lateralised PC Stem	Zimmer Biomet	Advice has been provided regarding a device removal	June 2016	Manufacturer's FSN
V27368	Mygo Stander	James Leckey Design	Advice has been provided regarding a device modification	March 2016	Manufacturer's FSN
V27210	FRED Easyport	Schiller AG	Advice has been provided regarding a device modification	March 2016	Manufacturer's FSN
V26786	ReoPro Filter kit	Eli Lily	Advice has been provided regarding the use of the device	February 2016	Manufacturer's FSN
V26895	Liko® Universal SlingBar 350, SlingBar 450 and SlingBar 600	Hill-Rom	Advice has been provided regarding a device modification	February 2016	Manufacturer's FSN
V26586	Enteral Nutrition ENfit Giving Set	Fresenius Kabi	Advice has been provided regarding the use of the device	January 2016	Manufacturer's FSN
V26544	CME Syringe Extension Sets 100-1725 & 100-172SLL	Caesarea Medical Electronics Limited	Advice has been provided regarding a device removal	January 2016	Manufacturer's FSN
V26251	GYNECARE THERMACHOICE™ III Thermal Balloon Ablation Silicone Catheter	Ethicon Inc.	Advice has been provided regarding a device removal	December 2015	Manufacturer's FSN
V26069	GlucoMen LX Sensor Test Strips	A.Menarini Diagnostics S.r.l.	Advice has been provided regarding use of the device	November 2015	Manufacturer's FSN1 Manufacturer's FSN2
V26596	T34 Ambulatory Syringe Pump	Caesarea Medical Electronics Limited	Advice has been provided regarding the use of the device	October 2015	Manufacturer's FSN
V25949	ProcedurePak® containing BD Plastipak Syringes	Mölnlycke Health Care AB	Advice has been provided regarding the use of the device	October 2015	Manufacturer's FSN

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V24665	Dolomite rollators: Futura, Melody, Legacy, Maxi+, Alpha, Symphony, Jazz 520 and Jazz 600	Invacare	Advice has been provided regarding changes/updates made to instructions for use	October 2015	Manufacturer's FSN
V25649	BD Plastipak Syringes, BD Oral Syringes	Becton Dickinson and Company Limited	Advice has been provided regarding the use of the device	September 2015	Manufacturer's FSN
V27708	Immunoassay Control, Immunoassay Premium Plus Control	Randox	Advice has been provided regarding a device modification	August 2015	Manufacturer's FSN
V24667	Liko® Viking® L, Viking® M, Viking® XL, and Viking® 300 Mobile Lifts	Hill-Rom	Advice has been provided regarding a device modification	June 2015	Manufacturer's FSN
V24017	Accu-Chek Spirit Combo insulin pump / Accu-Chek Spirit insulin pump	Roche Diabetes Care	Advice regarding the use of the device	May 2015	Manufacturer's FSN
V23462	Invacare® Leo®, Invacare® Orion® & Invacare® Comet® Scooters	Invacare	Advice regarding the use of the device	March 2015	Manufacturer's FSN
V23577	Birdie Lifter	Invacare	Advice has been provided regarding changes/updates made to instructions for use	March 2015	Manufacturer's FSN
V23309	CADD™ Medication Cassette Reservoir, 50ml	Smiths Medical	Advice has been provided regarding a device removal	February 2015	Manufacturer's FSN
V20596	Merck Serono pH Indicator Strips 0-6.0, Merck Serono pH Indicator Strips 2.0-9.0	Merck Serono	Advice regarding changes/updates made to instructions for use	November 2014	Manufacturers FSN
V22468	Medtronic MiniMed Enlite™ Glucose Sensor	Medtronic	Advice has been provided regarding a product removal	November 2014	Manufacturer's FSN
V22478	MiniMed Silhouette™ and Sure-TTM infusion sets	Medtronic	Advice has been provided regarding the use of the device	November 2014	Manufacturer's FSN
V22601	Perfect O2, Perfect O2V, Platinum S, Platinum 9	Invacare	Advice has been provided regarding a device modification	November 2014	Manufacturers FSN

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V22168	Accu-Chek® Spirit Combo insulin pumps	Roche Diabetes Care	Advice regarding the use of the device	September 2014	Manufacturers FSN
V17894	Flocare Infinity II enteral feeding pumps	Nutricia	Advice has been provided regarding a software upgrade	June 2014	Manufacturer's FSN
V20596	Merck Serono pH Indicator Strips 0-6.0, Merck Serono pH Indicator Strips 2.0-9.0	Merck Serono	Advice regarding changes/updates made to instructions for use	May 2014	Manufacturers FSN
V20868	Accu-Chek Mobile System	Roche Diabetes Care	Advice regarding the use of the device	May 2014	Manufacturer's FSN
V20981	Drive Walking Frames (10284-30 and 10284W-30)	Drive Medical	Advice regarding the use of the device	May 2014	Manufacturer's FSN
V20802	DETEX X-Ray Detectable Swabs	Synergy Health	Advice has been provided regarding a device removal	May 2014	Manufacturer's FSN
V20542	A200 Power Wheelchair / Skippi & Skippi Plus Power Wheelchair	Ottobock Healthcare	Advice has been provided regarding a device modification	April 2014	Manufacturer's FSN
V20491	Oxoid Antimicrobial Susceptibility Testing (AST) Discs - Meropenem MEM10	Thermofisher Scientific	Advice regarding the use of the device	April 2014	Manufacturer's FSN
V19644	Pegasus Alternating Mattresses X2 Capacitor, affecting Biwave, Cairwave, Trinova and Viaclin Pumps	ArjoHuntleigh	Advice has been provided regarding a device modification	March 2014	Manufacturer's FSN
V20097	Samaritan 500P	HeartSine	Advice has been provided regarding a software upgrade	February 2014	Manufacturer's FSN
V20264	Alaris® SmartSite® Needle-Free Valve	CareFusion International	Advice has been provided regarding a device removal	February 2014	Manufacturer's FSN
V19783	Comploglass F	Ivoclar Vivadent	Advice has been provided regarding a device removal	January 2014	Manufacturer's FSN
V19737	BD Plastipak™ 50mL Luer Lok Syringes	BD Medical	Advice regarding the use of the device	January 2014	Manufacturer's FSN
V19736	Kodak 2100 and Kodak 2200 Intraoral x-ray Systems	Carestream	Advice has been provided regarding a device modification	January 2014	Manufacturer's FSN

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V19091	SynReam Medullary Reamer Head 8.5mm	DePuy Synthes	Advice has been provided regarding a device removal	December 2013	Manufacturer's FSN
V19092	Accu-Chek® Aviva Combo Handset	Roche	Advice regarding the use of the device	October 2013	Manufacturer's FSN
V19001	Liko® SlingBar™ 350, SlingBar™ 360, SlingBar™ Wide 670, and SideBar™ Standard	Liko / Hill-Rom	Advice has been provided regarding a device modification	October 2013	Manufacturer's FSN
V19047	Power Chair, model Q600, Q600XL, Q600 Sport, Q6 Edge, Q600 Sport HD	Pride Mobility Products Limited	Advice has been provided regarding changes/updates made to instructions for use	October 2013	Manufacturer's FSN
V18608	Getinge 46-Series Washer Disinfector with PACS 300	Getinge	Advice has been provided regarding a device modification	August 2013	Manufacturer's FSN
V18007	Patterson Walking Sticks – 404 model	Patterson Medical	Advice has been provided regarding a device removal	June 2013	Manufacturer's FSN
V18008	Patterson Walking Frames	Patterson Medical	Advice has been provided regarding a device removal	June 2013	Manufacturer's FSN
V17822	CoaguChek XS; CoaguChek XS Plus; CoaguChek XS Pro	Roche	Advice regarding the use of the device	May 2013	Manufacturer's FSN
V17542	BD Plastipak 50ml Luer Lok Syringe	Becton Dickinson and Company Limited	Advice has been provided regarding a device removal	April 2013	Manufacturer's FSN
V17378	Invacare REA Assist wheelchairs	Invacare	Advice has been provided regarding changes/updates made to instructions for use	March 2013	Manufacturer's FSN
V17075	Oxford Advance Hoist	Joerns Healthcare Limited	Advice has been provided regarding a device modification	February 2013	Manufacturer's FSN
V16981	ML 301 examination lamp with Ondal Acrobat® Swing spring arm	Gebruder Martin GmbH & Co. KG	Advice has been provided regarding a device removal	January 2013	Manufacturer's FSN
V16448	Freeway Hoists / Ta Xtra Hoists	Prism Medical UK	Advice has been provided regarding a device modification	November 2012	Manufacturer's FSN
V16769	Liko Ceiling Mounted Overhead Rail Systems	Hill-Rom Luleå	Advice has been provided regarding a device modification	November 2012	Manufacturer's FSN

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V16038	PSX Proximate® Skin Staple Extractor	Ethicon Endo-Surgery	Advice has been provided regarding a device removal	October 2012	Manufacturer's FSN
V16271	REA Azalea Base	Invacare	Advice regarding the use of the device	October 2012	Manufacturer's FSN
V15772	Samaritan 300P	HeartSine	Advice has been provided regarding a software upgrade	September 2012	Manufacturer's FSN
V15947	Liko Bathing Chair	Liko AB	Advice has been provided regarding changes/updates made to instructions for use	September 2012	Manufacturer's FSN
V15533	Minivator Bath Bliss Reclining Bathlift 311	Handicare Limited	Advice has been provided regarding a device modification	August 2012	Manufacturer's FSN
V15066	FreeSpan Traverse and FreeSpan UltraTwin Traverse Freestanding Lift Systems	Hill-Rom / Liko	Advice has been provided regarding changes/updates made to instructions for use	July 2012	Manufacturer's FSN
V15355	KleenSpec Disposable Vaginal Specula	Welch Allyn	Advice has been provided regarding the use of the device	July 2012	Manufacturer's FSN
V15322	Neonatal and paediatric endotracheal tube clamp/holders	EMS Medical	Advice has been provided regarding a device removal	July 2012	MHRA Medical Device Alert
V15978	Sabina and Capella Sit-to-Stand mobile lifts	Liko AB	Advice has been provided regarding a device modification	June 2012	Manufacturer's FSN Manufacturer's FSN
V14956	Harrier Range Wheelchairs	Invacare	Advice regarding the use of the device	May 2012	Manufacturer's FSN
V14764	Birdie & Flamingo Lifters	Invacare	Advice has been provided regarding a device modification	May 2012	Manufacturer's FSN
V14969	Zimma Walking Frame	Invacare	Advice has been provided regarding a device modification	May 2012	Manufacturer's FSN
V14583	Hera II Bathing and Toileting Chair	Ergolet	Advice has been provided regarding a device modification	April 2012	Manufacturer's FSN
V14241	Avant, Avant LW and Salsa Walkers	Etac Supply Center AB	Advice has been provided regarding a device modification	February 2012	Manufacturer's FSN
V14306	Freeway Mobile Hoists	Prism Medical UK	Advice has been provided regarding a device modification	February 2012	Manufacturer's FSN

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V13274	Walker Etac ONO	Etac AB	Advice has been provided regarding a device modification	February 2012	Manufacturer's FSN
V14609	GH3/GH1 Trolley	Guldmann	Advice has been provided regarding a device modification	February 2012	Manufacturer's FSN
V13699	Vector TAS Modular Driver	Ormco Europe B.V.	Advice has been provided regarding changes/updates made to instructions for use	January 2012	Manufacturer's FSN
V14154	Syngo.Plaza	Siemens AG Healthcare Sector	Advice has been provided regarding a software upgrade	January 2012	Manufacturer's FSN
V14151	Syngo.Plaza	Siemens AG Healthcare Sector	Advice has been provided regarding a software upgrade	January 2012	Manufacturer's FSN
V13634	Sterimar Isotonic 100ml	Church & Dwight UK Limited	Advice has been provided regarding a device removal	December 2011	Manufacturer's FSN
V13906	NP150 Mattress	Hill Rom	Advice has been provided regarding changes/updates made to instructions for use	December 2011	Manufacturer's FSN
V13456	Level 1® D/DI-60HL Normothermic IV Administration Sets: D-60HL, DI-60HL	Smiths Medical	Advice has been provided regarding a device removal	November 2011	Manufacturer's FSN
V13456	HOTLINE® Disposable Administration Sets: L-70, L- 70NI, L-80, L-270 and L-370	Smiths Medical	Advice has been provided regarding a device removal	November 2011	Manufacturer's FSN
V13356	Puma, Beatle, Alex and Ibis XP Power Wheelchairs	Handicare	Advice has been provided regarding a device modification	November 2011	Manufacturer's FSN
V13343	REA Assist Wheelchairs	Invacare	Advice regarding the use of the device	November 2011	Manufacturer's Technical Bulletin
V10346	X220, X221, X312 and X313 Bariatric Commodes	Cefndy Healthcare	Advice has been provided regarding a device modification	November 2011	Manufacturer's FSN
V13303	Abbott FreeGo enteral feeding pump	Abbott Laboratories Ireland Limited	Advice has been provided regarding a device modification	November 2011	Manufacturer's FSN

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V12925	Drive Medical Nimbo Paediatric Walkers	Drive Medical	Advice has been provided regarding changes/updates made to instructions for use	September 2011	Manufacturer's FSN
V12924	Drive WA007 Rollators	Drive Medical	Advice has been provided regarding a device modification	August 2011	Manufacturer's FSN
CP9967	Explorer Loop 4 Wheeled Rollators	Murrays Medical Equipment Limited	Advice has been provided regarding a device removal	August 2011	Manufacturer's Customer Letter
V13017	Endres Riviera Bathlift	Drive Medical	Advice has been provided regarding changes/updates made to instructions for use	August 2011	Manufacturer's FSN
V12469	Linet Eleganza Standard & Deluxe Model Bedframes	Linet	Advice has been provided regarding a device modification	July 2011	Manufacturer's FSN
V12351	Wispa Portable Hoist and Attachment Handle	Chiltern Invadex UK Limited	Advice has been provided regarding a device modification	July 2011	Manufacturer's FSN
V12466	Pressure Area Care Mattresses and Cushions	Talley Group	Advice has been provided regarding changes/updates made to instructions for use	July 2011	Manufacturer's FSN
V9506	CERAGEM-E Massage Bed	CERAGEM Co. Limited	Advice has been provided regarding changes/updates made to instructions for use	July 2011	Manufacturer's FSN
V12465	ArjoHuntleigh lifting poles with an adjustable strap and handle - ROLKO strap and handle	ArjoHuntleigh	Advice has been provided regarding a device removal	July 2011	Manufacturer's FSN
V12399	Marus brand LuxStar Dental Lights (Model OL1000)	Marus	Advice has been provided regarding a device modification	July 2011	Manufacturer's FSN
V12134	OXFORD Easytrack 2, 3 & 4 Post Systems	Joerns Healthcare	Advice has been provided regarding use of the device	June 2011	Manufacturer's FSN
V12482	Waverly Glen Transactive (TA) Hoists and Waverly Glen Transportable (TP) Hoists	Prism Medical UK	Advice has been provided regarding a device modification	June 2011	Manufacturer's FSN
V12187	Moving Solutions Slings	Nottingham Rehab Supplies	Advice has been provided regarding changes/updates made to instructions for use	June 2011	Manufacturer's FSN

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V8535	Xcelerate Ceramic 4:1 Cutting Blocks	Stryker Orthopaedics	Advice has been provided regarding a device removal	June 2011	Manufacturer's FSN
V12061	PELIspec vaginal speculums	Pelican Feminine Healthcare Limited	Advice has been provided regarding a device removal	May 2011	Manufacturer's FSN
V11933	LogiCal®, NovaTrans®, and TranStar® Invasive Pressure Monitoring Systems	Smiths Medical	Advice has been provided regarding a device removal	May 2011	Manufacturer's FSN
V12142	Scanbed 400 Nursing Bed	Invacare	Advice has been provided regarding changes/updates made to instructions for use	May 2011	Manufacturer's FSN
V11405	Romachair Model 4730 / 4740	Roma Medical	Advice has been provided regarding a device modification	March 2011	Manufacturer's FSN
V11437	Applix Smart and Applix Vision Nutrition Enteral Feeding Pumps	Fresenius Kabi Limited	Advice has been provided regarding a device modification	March 2011	Manufacturer's FSN
V11227	Quickie Neon Swing Away Wheelchair	Sunrise Medical	Advice has been provided regarding a device modification	February 2011	Manufacturer's FSN
V11133	Mikro 120	Andreas Hettich GmbH & Co	Advice has been provided regarding a device modification	January 2011	Manufacturer's FSN
V8682	Action 3 and Action 4 Manual Wheelchairs	Invacare	Advice has been provided regarding changes/updates made to instructions for use	January 2011	Manufacturer's FSN
V11096	Mobility Powerchairs Control System Changes	Invacare	Advice has been provided regarding the use of the device	January 2011	Manufacturer's FSN
V11339	Samba Chair (Product Codes 8801, 8802, 8803, 8804, 8810)	G&S Smirthwaite Limited	Advice has been provided regarding a device modification	January 2011	Manufacturer's FSN
V10897	Typhoon II Power Wheelchair with Stability Lock	Invacare	Advice has been provided regarding a device modification	December 2010	Manufacturer's FSN
V10177	Seca 955 and Seca 959 chair scales	Seca	Advice has been provided regarding a device modification	October 2010	Manufacturer's FSN
V10465	Peristeen Anal Irrigation System	Coloplast	Advice has been provided regarding changes/updates made to instructions for use	October 2010	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V10419	Relactagel	Kora Healthcare	Advice has been provided regarding a device removal	October 2010	Manufacturer's FSN
V10480	Static Mattresses	Park House Healthcare	Advice has been provided regarding changes/updates made to instructions for use	October 2010	Manufacturer's FSN
V10222	All Freeway Shower Chairs with integral drop down armrests	Prism Medical UK	Advice has been provided regarding a device modification	September 2010	Manufacturer's FSN
V10525	SOPIRA Carpule Needles	Heraeus	Advice has been provided regarding a device removal	September 2010	Manufacturer's FSN
V10188	Oxford Weigh-scale item OP97000	Joerns Healthcare	Advice has been provided regarding the use of the device	August 2010	Manufacturer's FSN
V10178	Pride Riser Recliner	Pride Mobility Products	Advice has been provided regarding changes/updates made to instructions for use	August 2010	Manufacturer's FSN
V10587	Oxford Midi 150A Hoists	Joerns Healthcare	Advice has been provided regarding the use of the device	July 2010	Manufacturer's FSN
V9998	Comfort 4 Therapy Chair	Digitherm	Advice has been provided regarding a device modification	July 2010	Manufacturer's FSN
V9585	SleepStyle™ Series CPAP Power Cord Product Replacement	Fisher & Paykel Healthcare	Advice has been provided regarding a device modification	July 2010	Manufacturer's FSN
V1408	ArjoHuntleigh alternating pressure therapy systems	ArjoHuntleigh	Advice has been provided regarding a device modification	June 2010	Manufacturer's FSN
V9656	LikePak 20 and Lifepak 20e	Physio Control	Advice has been provided regarding a device modification	June 2010	Manufacturer's FSN
V9819	Trachidress	Kapitex Healthcare Limited	Advice has been provided regarding a device removal	March 2010	Manufacturer's FSN
V8911	BHM Medical Inc. Hoists	BHM Medical Inc.	Advice has been provided regarding a device modification	February 2010	Manufacturer's FSN
V8947	Dycal Radiopaque Calcium Hydroxide Composition Cavity Base/Liner	DENTSPLY Caulk	Advice has been provided regarding a device removal	February 2010	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V9006	Ondal Acrobat 2000 Sprung Arm used to carry HELION and XENION surgical lights and monitors	TRUMPF Medizin Systeme GmbH	Advice has been provided regarding a device modification	February 2010	Manufacturer's FSN
V11627	Harmony LA, LC 500 and LA 700 Surgical Lighting and Media System	Steris	Advice has been provided regarding a device modification	February 2010	Manufacturer's FSN
V7581	New Bug Push Chair	Ormesa	Advice has been provided regarding changes/updates made to instructions for use	February 2010	Distributor's FSN
V8642	Hill-Rom beds with Monkey Pole (Lifting Pole)	Rolko Kohlgrüber GmbH	Advice has been provided regarding a device removal	January 2010	Manufacturer's FSN
V8682	Action 3 and Action 4 Manual Wheelchairs	Invacare	Advice has been provided regarding changes/updates made to instructions for use	January 2010	MHRA Medical Device Alert
V8917	Appollo Special Needs Bathing Products, models: Elegance, Excalibur and Apollo	Reva Industries Limited	Advice has been provided regarding a device modification	December 2009	Manufacturer's FSN
V7832	Thermo contour mattress	Barrington Healthcare International Limited	Advice has been provided regarding changes/updates made to instructions for use	December 2009	Manufacturer's FSN
V8352	Oxford Hoists	Joerns Healthcare	Advice has been provided regarding the use of the device	November 2009	Manufacturer's FSN
V8391	Oxford Slings	Joerns Healthcare	Advice has been provided regarding changes/updates made to instructions for use	November 2009	Manufacturer's FSN
V7962	Ondal Acrobat 2000 spring arms used in ML, marLUX and marLED operating light suspensions	Gebrüder Martin GmbH & Co. KG	Advice has been provided regarding a device modification	August 2009	Manufacturer's FSN
V8038	Birdie Patient Lifter	Invacare	Advice has been provided regarding a device modification	August 2009	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V9970	Permobil Wheelchairs	Permobil	Advice has been provided regarding changes/updates made to instructions for use	July 2009	Manufacturer's FSN
V7741	AquaJoy Premier Plus and Junior Plus Bathlifts	AquaJoy Bathlifts Limited	Advice has been provided regarding changes/updates made to instructions for use	July 2009	Manufacturer's FSN
V7731	Rea Azalea Base Wheelchair	Invacare	Advice has been provided regarding a device modification	July 2009	Manufacturer's FSN
V8196	Rea Assist Backrest Bow	Invacare	Advice has been provided regarding a device modification	July 2009	Manufacturer's FSN
V7845	Escape Lite Wheelchairs	Patterson Medical, formerly Days Healthcare	Advice has been provided regarding the use of the device	July 2009	Manufacturer's FSN
V7835	AC2000 Spring Arm	Ondal Industrietechnik	Advice has been provided regarding a device modification	June 2009	Manufacturer's FSN
V11227	Icelock® Expulsion Valve 551	Össur	Advice has been provided regarding a device removal	June 2009	Manufacturer's FSN
V8301	Passive Patient Lifts and Ceiling Lifts	ArjoHuntleigh	Advice has been provided regarding a device modification	June 2009	Manufacturer's FSN
V7431	T34 Sytinger Driver	CME McKinley	Advice has been provided regarding a device modification	May 2009	Manufacturer's FSN
V7404	Harrier Range (Plus, HD & XHD) wheelchairs	Invacare	Advice has been provided regarding changes/updates made to instructions for use	May 2009	Manufacturer's FSN
V7581	New Bug Push Chair	Ormesa	Advice has been provided regarding changes/updates made to instructions for use	May 2009	Manufacturers Revised IFU
V7078	Bed Side Rails - 1025 range, 1031 range, SP 1027 range	Corona Medical	Advice has been provided regarding the use of the device	March 2009	Manufacturer's FSN
V7043	AED Plus	Zoll	Advice has been provided regarding a device modification	February 2009	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V6938	All models of Jazzy, Quantum and LX battery powered wheelchairs	Pride Mobility Limited	Advice has been provided regarding changes/updates made to instructions for use	February 2009	MHRA Medical Device Alert
V2774	Flamingo hoist	Invacare	Advice has been provided regarding a device modification	February 2009	Manufacturer's FSN
V6918	Carina Home	Drager Medical	Advice has been provided regarding a device modification	January 2009	Manufacturer's FSN
V6848	Aluminium Walking Frames	Days Healthcare	Advice has been provided regarding a device modification	January 2009	Manufacturer's FSN
V7143	Posture Belt for use with Mobile Advance Seat, Contoured Advance Set, Squiggles Advance Seat and Squiggles Early Sitting System	Leckey	Advice has been provided regarding a device removal	January 2009	Manufacturer's FSN
V7041	Lifting Table Diagnostic 1171	WaveLight AG	Advice has been provided regarding a device modification	January 2009	Manufacturer's FSN
V6773	Alaris PK Syringe Pump	Cardinal Health	Advice has been provided regarding the use of the device	January 2009	Manufacturer's FSN
V7228	Frimley folding stool model AA1550	Homecraft Roylan Limited	Advice has been provided regarding a device modification	January 2009	Manufacturer's FSN
V6996	Action® 2000 manual wheelchair	Invacare	Advice has been provided regarding a device modification	January 2009	Manufacturer's FSN
V3665	Action 3 Wheelchairs fitted with ratchet reclining backrest	Invacare	Advice has been provided regarding changes/updates made to instructions for use	December 2008	Manufacturer's FSN
V6770	Liko Mobile Patient Lifts: Uno, Viking S, Viking XS, LikoLight	Liko AB	Advice has been provided regarding a device modification	December 2008	Manufacturer's FSN
V2391	Strider Maxi & Strider Midi 4 Plus Scooters	Days Healthcare	Advice has been provided regarding a device modification	November 2008	Manufacturer's FSN
V6483	Flocare® Infinity Enteral Feeding Pump	Nutricia	Advice has been provided regarding a software upgrade	November 2008	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V4050	Transportation of Storm 3 Range (including Storm 3 TT), Typhoon 1 & 2 power wheelchairs	Invacare	Advice has been provided regarding changes/updates made to instructions for use	November 2008	Manufacturer's FSN
V6810	Avantgarde Back Tube	Otto Bock Healthcare	Advice has been provided regarding a device modification	September 2008	Manufacturer's FSN
V6574	Battery charger for Mermaid and Historic Oxford hoists	Joerns Healthcare	Advice has been provided regarding use of the device	September 2008	Manufacturer's FSN
V6139	Siroclave	Sirona	Advice has been provided regarding a device modification	August 2008	Manufacturer's FSN
V6125	Baby Sleepsafe Monitor, model AE 010 M	Axminister Electronics Limited	Advice has been provided regarding a device modification	August 2008	Manufacturer's FSN
V6188	Reliant lifter 100 / 150 / 200 / 250	Invacare	Advice has been provided regarding changes/updates made to instructions for use	August 2008	Manufacturer's FSN
V6655	Sunrise Medical Manual and Powered Wheelchairs	Sunrise Medical	Advice has been provided regarding changes/updates made to instructions for use	July 2008	Manufacturer's FSN
V6014	LIFEPAK CR Plus and/or LIFEPAK EXPRESS Defibrillators	Medtronic Limited	Advice has been provided regarding a device modification	July 2008	Manufacturer's FSN
V6368	2" and 4" Savannah raised toilet seats	Homecraft Roylan	Advice has been provided regarding a device modification	July 2008	Manufacturer's FSN
V4180	Walking frames	Trulife	Advice has been provided regarding a device modification	June 2008	Manufacturer's FSN
V5837	Liko Universal SlingBar	Liko AB	Advice has been provided regarding a device modification	June 2008	Manufacturer's FSN
V6016	Medi-Tec Classic Hoist	Aidservice Limited	Advice has been provided regarding a device modification	June 2008	Manufacturer's FSN
V6178	Kaye Posture Control Walker	Quest 88	Advice has been provided regarding a device modification	May 2008	Manufacturer's FSN
V6791	Maxi Sky 600 – Infrared (IR) System	Arjo Technical	Advice has been provided regarding a device modification	May 2008	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V5907	Power Module (part of RiwoMobile)	Richard Wolf GmbH	Advice has been provided regarding a device removal	May 2008	Manufacturer's FSN
V4152	Huntleigh birthing bed mattresses used with Birthright Bed models 35000 (manual) and 170000 (electric) versions and Hoskins Birthcare bed models L05 and L10	Huntleigh Healthcare	Advice has been provided regarding changes/updates made to instructions for use	April 2008	Manufacturer's FSN
V4069	AKW 2000 series shower seat	ADW MediCare	Advice has been provided regarding a device modification	March 2008	Manufacturer's FSN
V4025	Ambulift / Ambulift Power and Ambulift Classic Lifters	Arjo	Advice has been provided regarding a device modification	March 2008	Manufacturer's FSN
V4024	NovaTrans, Transtar Invasive Pressure Monitoring Kits with Trigger Flush Device	Smiths Medical	Advice has been provided regarding changes/updates made to instructions for use	February 2008	Manufacturer's FSN
V5905	Intelect	Chattanooga Group	Advice has been provided regarding a software upgrade	January 2008	Manufacturer's FSN
V3912	Birthright beds and Hoskins Birthcare beds	Huntleigh Healthcare	Advice has been provided regarding a device modification	January 2008	Manufacturer's FSN
V3855	Stryker stretchers	Stryker	Advice has been provided regarding a device modification	January 2008	Manufacturer's FSN
V3866	Applix Smart Enteral Feeding Pumps	Fresenius Kabi	Advice has been provided regarding the use of the device	January 2008	Manufacturer's FSN
V4015	InChair Sling	Care & Independence Systems Limited	Advice has been provided regarding changes/updates made to instructions for use	January 2008	Manufacturer's FSN
V3946	Module DPS	Fresenius Kabi	Advice has been provided regarding a device modification	January 2008	Manufacturer's FSN
V3946	Module DPS	Fresenius Kabi	Advice has been provided regarding a device modification	January 2008	Manufacturer's FSN
V3656	Active Pump	Invacare	Advice has been provided regarding a device modification	December 2007	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V3852	Phase Cells	Park House Healthcare	Advice has been provided regarding a device modification	December 2007	Manufacturer's FSN
V3665	Action 3 Wheelchairs fitted with ratchet reclining backrest	Invacare	Advice has been provided regarding changes/updates made to instructions for use	December 2007	Manufacturer's FSN
V3798	Konstant Battery Charger 24V 6A	Lomax Mobility & Sunrise Medical	Advice has been provided regarding a device modification	November 2007	Manufacturer's FSN
V3652	Kimba Spring Paediatric Buggy	Ottobock Healthcare	Advice has been provided regarding a device modification	October 2007	Manufacturer's FSN
V3665	Action 3 Wheelchairs fitted with ratchet reclining backrest	Invacare	Advice has been provided regarding a device modification	October 2007	Manufacturer's FSN
V3693	Frazier and Poole Suction Instruments	ConMed Corporation	Advice has been provided regarding a device removal	September 2007	Manufacturer's FSN
V3652	Kimba Spring Range	Otto Bock Healthcare	Advice has been provided regarding a device modification	July 2007	Manufacturer's FSN
V3348	Contoura 880 beds	Huntleigh Healthcare	Advice has been provided regarding a device modification	May 2007	Manufacturer's FSN
V3262	Getinge models 8666, 8668, 46-2, 46-4, 46-5 Washer Disinfectors and S-607, S-608, S-617, S-618 and SP1000 Flusher Disinfectors	Getinge Disinfection AB	Advice has been provided regarding a device modification	April 2007	Manufacturer's FSN
V3157	LIFEPAK CR Plus and/or LIFEPAK EXPRESS Defibrillators	Medtronic Limited	Advice has been provided regarding a device modification	March 2007	Manufacturer's FSN
V2961	Kjaerulff Mini Lift Stand Aids	Kjaerulff A/S	Advice has been provided regarding a device modification	December 2006	Manufacturer's FSN
V3138	Spectra Plus powered wheelchair	Invacare	Advice has been provided regarding changes/updates made to instructions for use	December 2006	Manufacturer's FSN
V2907	REMstar Heated Humidifier	Philips Respironics	Advice has been provided regarding a device removal	October 2006	Manufacturer's FSN

Case ID*	Product	Manufacturer	Type	Date Initiated	Link to FSN
V2754	Jay® J2 wheelchair backs	Sunrise Medical	Advice has been provided regarding changes/updates made to instructions for use	September 2006	MHRA Medical Device Alert
V2349	Rea Assist Armrests	Invacare	Advice has been provided regarding a device modification	April 2006	Manufacturer's FSN
V2357	Total Knees, models 1100, 1900, 2000 & 2100	Össur	Advice has been provided regarding a device removal	March 2006	Manufacturer's FSN

** Based on feedback received, the HPRA has also included on this Field Safety Notice Summary Sheet a 'Case ID' for each listing. This is the HPRA's unique identifier for the individual FSN, and may be used by healthcare establishments in their systems as appropriate.*