



EU Declaration of Conformity



repose[®]

Pressure Relief Devices & Accessories

(See Appendix 1 for product list, codes and applicable UDI-DI)



Manufacturers Name:

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This declaration of conformity is issued under the sole responsibility of Frontier Therapeutics Limited. We hereby declare that the medical device(s) specified above and in Appendix 1 meet the provision of the **Regulation (EU) MDR 2017/745** for medical devices.

This declaration is supported by the Quality Management Systems approval to ISO 13485:2016 issued by BSI Group (Certificate Number: MD 74431). All supporting documentation is retained at the premises of the manufacturer.

For evaluation of compliance with this regulation, the harmonised standards detailed in Appendix 2 were applied.

Risk Class: Medical device, Class I

Person responsible for making the declaration:

Name, Surname: **Simon Bosley**

Position/Title: **Technical Director**

Date: **25.08.2023**

Signature:

Appendix 1 - Product list

UDI-DI	Product Code (MPN)	Description	UDI-DI	Product Code (MPN)	Description
5056279301183	6020000	Repose Single Long Footprotector (Bagged)	5056279302227	651110401	Repose Protezione piede PLUS singolo x 10 e pompa
5056279301190	6020001	Repose Pair Long Footprotector (Bagged)	5056279302234	6511105	Repose Footprotector PLUS (Pair) x10 no pump
5056279301206	6020002	Repose Single Footprotector and Pump (10 Pack)	5056279302241	6511106	Repose Footprotectors PLUS (Pair) and Pump (10 Pack)
5056279301213	6020003	Repose Footprotectors (Pair) and Pump	5056279302258	6511110	Repose Footprotector Plus (Pair) (Bulk Pack 10)
5056279301220	6021000	Repose Single Long Footprotector and Pump	5056279302265	651111001	Repose Protezione piede PLUS coppia x 10 e pompa
5056279301237	6021001	Repose Single Long Footprotector and Pump (10)	5056279302272	651111101	Repose Protezione piede PLUS coppia e pompa x 10
5056279301244	6021100	Repose Long Footprotectors (Pair) and Pump	5056279302289	651111401	Repose Protezione piede PLUS singolo e pompa x 10
5056279301251	6021102	Repose Long Footprotectors (Pair) and Pump (Pack of 10)	5056279302296	6520100	Repose Small Footprotector (Bulk Pack 10) with pump
5056279301992	6500020	Repose Single Footprotector (Bagged)	5056279302302	6521100	Repose Small Footprotectors (Pair) and Pump
5056279302005	6500100	Repose Footprotectors (Pair) (Bagged)	5056279302319	6521101	Repose Small Footprotectors (Pair) and Pump (10 Pack)
5056279302012	6500101	Repose Footprotectors (Pair) (Bagged) x 10 - no pump	5056279302326	6521102	Repose Small Footprotectors (Single) and Pump
5056279302029	6500200	Repose Footprotector (Pair) (Bulk Pack 10)	5056279302333	6521103	Repose Small Footprotectors (Pair) and Pump
5056279302036	6500201	Repose Long Footprotectors (Pair) (Bulk Pack 10)	5056279302340	6530100	Repose Extra Small Footprotector (Bulk Pack 10) with pump
5056279302043	6500202	Repose Footprotector (Pair) (Bulk Pack)	5056279302357	6531100	Repose Extra Small Footprotectors (Pair) and Pump
5056279302050	6501020	Repose Single Footprotector and Pump	5056279302364	6531101	Repose Extra Small Footprotectors (Pair) and Pump (10 Pack)
5056279302067	6501021	Repose Single Footprotector and Pump	5056279302371	6531102	Repose Extra Small Footprotectors (Single) and Pump
5056279302074	6501100	Repose Footprotectors (Pair) and Pump	5056279302388	6531103	Repose Extra Small Footprotectors (Pair) and Pump
5056279302081	650110001	Repose Protezione piede x2 e pompa	5056279302395	6540100	Repose Small Footprotector Plus (Bulk Pack 10) with pump
5056279302098	6501101	Repose Footprotectors (Pair) and Pump (10 Pack)	5056279302401	6541100	Repose Small Footprotectors Plus (Pair) and Pump
5056279302104	6501102	Repose Footprotectors (Pair) and Pump	5056279302418	6541101	Repose Small Footprotectors Plus (Pair) and Pump (10 Pack)
5056279302111	6501103	Repose Footprotector (10 Pr) and Pump	5056279302425	6541103	Repose Small Footprotectors Plus (Single) and Pump
5056279302128	6501104	Repose Footprotector (20 Pr) and Pump	5056279302432	6550100	Repose Extra Small Footprotector Plus (Bulk Pack 10) with pump
5056279302135	6501105	Repose Footprotector Lg(10S) and Pump	5056279302449	6551100	Repose Extra Small Footprotectors Plus (Pair) and Pump
5056279302142	6501106	Repose Footprotector Lg (Pr) and Pump x	5056279302456	6551101	Repose Extra Small Footprotectors Plus (Pair) and Pump (10 Pack)
5056279302159	6511100	Repose Footprotector PLUS (Pair) and pump	5056279302463	6551103	Repose Extra Small Footprotectors Plus (Single) and Pump
5056279302166	651110001	Repose Protezione piede PLUS x2 e pompa	5056279302548	6700100	Repose Wedge (Bagged)
5056279302173	6511101	Repose Footprotector PLUS (Single) and pump	5056279302555	6700101	Repose Wedge (Bulk Pack)
5056279302180	651110101	Repose Protezione piede PLUS singolo e pompa	5056279302562	6700102	Repose Wedge (with Strap) (Bulk Pack 10)
5056279302197	6511102	Repose Footprotector PLUS (Single) In Zip Bag	5056279302579	6710100	Repose Wedge (with Strap) (Bagged)
5056279302203	6511103	Repose Footprotector PLUS (Pair) In Zip Bag	5056279302586	6710101	Repose Wedge (with Strap) (Bagged) x 10
5056279302210	6511104	Repose Single Footprotector PLUS and Pump	5056279302593	6711100	Repose Wedge (with Strap) and Pump
5056279302661	6711114	Repose Wedge (With PU Strap) with Pump (10 Pack)	5056279302616	6711101	Repose Wedge (with Strap) and Pump (10 Pack)
5056279302678	6750000	Repose Flex - Extra Small 1 Flex and pump	5056279302623	6711110	Repose Wedge (with PU Strap) Bagged
5056279302685	6750001	Repose Flex - Small 1 Flex and pump	5056279302630	6711111	Repose Wedge (with PU Strap) with pump
5056279302692	6750002	Repose Flex - Standard 1 Flex and pump	5056279302647	6711112	Repose Wedge (with PU Strap) x10 with small pump (Bulk Pack)

5056279302890	6821100	Wedge - Large	5056279302654	6711113	Repose Wedge (with PU Strap) x10 no Pump
5056279303224	6910100	Repose Wedge (50cm) (Bagged)	5056279303972	7821100	Wedge - Large
5056279303231	6920100	Repose Wedge (50cm with Strap)	5056279303989	7921100	Repose Wedge (50cm) and Pump 10 singles
5056279303248	6921100	Repose Wedge (50cm) and Pump	5056279303996	7921101	Repose Wedge (50cm 5 Tubes) and Pump 10 singles
5056279303255	6921101	Wedge Without Strap - Large	5056279304009	7930001	Repose Sole Protector and Pump 10 singles
5056279303262	6930000	Repose Sole Protector x 1 in zip lock bag	5056279304016	793000101	Repose Sole Protector e pompa 10 singloe
5056279303279	6930001	Repose Sole Protector x 1 with Small Pump	5056279304153	675000001	Repose Flex - extra piccolo e pompa
5056279303286	693000101	Repose Sole Protector x 1 e pompa	5056279304160	675000101	Repose Flex - piccolo e pompa
5056279303293	6930009	Repose Sole Protector bagged x 10 no Pump	5056279304177	675000201	Repose Flex - standard e pompa
5056279303309	6930010	Repose Sole Protector x 10 with Small Pump	5056279304184	760110001	TRAVERSA PER LETTIGHE E POMPA
5056279303514	7501106	Repose Footprotector Lg (Pr) and Pump - 10 singles	5056279304191	775000001	Repose Flex - extra piccolo e pompa
5056279303620	7021000	Repose 1 Long Footprotector and pump 10 singles	5056279304207	775000101	Repose Flex - piccolo e pompa
5056279303637	7021100	Repose Long Footprotectors (Pair) and Pump - 10 singles	5056279304214	775000201	Repose Flex - standard e pompa
5056279303781	7501020	Repose Single Footprotector and Pump 10 singles	5056279304245	6542000	Repose Foot Protector with Magnafix - Standard Size - 4 Layers (Pair)
5056279303798	7501021	Repose Footprotectors and pumps - 10 singles	5056279304252	6542001	Repose Foot Protector with Magnafix - Large Size - 4 Layers (Pair)
5056279303804	7501100	Repose Footprotectors (Pair) and Pump - 10 singles	5056279304269	6500300	4 Layer Standard Footprotector with Magnafix (Pair) (Bulk Pack 10)
5056279303811	7501102	Repose Footprotector (Pairs) and Pumps - 10 singles	5056279304276	6500301	4 Layer Large Footprotector with Magnafix (Pair) (Bulk Pack 10)
5056279303828	7501106	Repose Footprotector Lg (Pr) and Pump - 10 singles	5056279304306	7542000	4 Layer Footprotector with Magnafix (Pair) - Standard Size
5056279303835	7511100	Repose Footprotector PLUS (Pair) and pump - 10 singles	5056279304313	7542001	4 Layer Footprotector with Magnafix (Pair) - Large Size
5056279303842	7511101	Repose Footprotector plus (Singles) and pump - 10 singles	5056279304610	7750002	Repose Flex - Standard (1 Flex and pump)
5056279303859	751110101	Repose Protezione piede PLUS singolo e pompa - 10 singole	5056279304627	7521100	Small Foot Protector (pair) and pump
5056279303897	7701100	Repose Wedge and Pump 10 singles	5056279304634	6750000	Repose Flex - Extra Small
5056279303903	7711100	Repose Wedge (with Strap) and Pump 10 singles	5056279304641	6750010	Repose Flex - Extra Small
5056279303910	771110001	Repose Cuscino di sostegno 10 single	5056279304658	6750110	Repose Flex - Extra Small
5056279304696	6750111	Repose Flex - Small	5056279304665	6750210	Repose Flex - Extra Small
5056279304702	6750211	Repose Flex - Small	5056279304672	6750001	Repose Flex - Small
5056279304719	6750002	Repose Flex - Standard	5056279304689	6750011	Repose Flex - Small
5056279304726	6750012	Repose Flex - Standard	5056279305242	6921001	Wedge Without Strap - Large
5056279304733	6750112	Repose Flex - Standard	5056279305259	6921010	Wedge Without Strap - Large
5056279304740	6750212	Repose Flex - Standard	5056279305266	6921011	Wedge Without Strap - Large
5056279304795	7750000	Repose Flex - Extra Small	5056279305273	7921011	Wedge Without Strap - Large
5056279304801	7750001	Repose Flex - Small	5056279305297	6921110	Wedge Without Strap - Large
5056279304818	7750002	Repose Flex - Standard	5056279305747	6922001	Repose Wedge Without Strap Large x1
5056279304825	6260001	Repose Foot Protector Lite Standard	5056279305754	6922011	Repose Wedge Without Strap Large x1 & Pump x1
5056279304870	6711115	Wedge with Extra Long TPU Strap	5056279305761	6922101	Repose Wedge Without Strap Large x10 & Pump x10
5056279304887	6711116	Wedge with Extra Long TPU Strap	5056279305198	6821010	Wedge - Large
5056279304894	6711117	Wedge with Extra Long TPU Strap	5056279305228	6821110	Wedge - Large
5056279304900	6711118	Wedge with Extra Long TPU Strap	5056279305235	6821011	Wedge - Large
5056279305181	6821001	Wedge - Large	5056279306782	6760013	Repose Flex without strap, 1x Small Pump, 1x Repose Flex PU Cover
5056279306799	6760012	Repose Flex without strap (Bagged), 1x Repose Flex PU Cover	5056279306805	6760014	Repose Flex (without strap) with PU Cover
5056279306812	6760011	Repose Wedge without strap, 1x Small Pump, 1x Repose Wedge PU Cover	5056279306829	6760010	Repose Wedge without strap, 1x Small Pump, 1x Repose Wedge PU Cover
5056279306836	6760009	Repose Wedge (without Strap) Bagged	5056279306843	6711103	Repose Wedge (without strap) with PU Cover
5056279306881	6760013	Repose® Flex without strap standard x1 & Cover x1 & Pump x1	5056279306898	6760012	Repose® Flex without strap (Bagged) standard x1 & Cover x1
5056279306904	6760010	Repose® Wedge Without Strap standard x1 & Cover x1 & Pump x1	5056279306911	6711103	Repose® Wedge Without Strap Standard (Bagged) x1 & Cover x1

5056279306140	6760000	Wedge Standard Cover	5056279306164	6760002	Flex Cover
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Note – This includes all derivatives/variants and sizes of the above-stated products.

Appendix 2

Standard	Description
BS EN ISO 9001:2015	Quality Management Systems.
BS EN ISO 13485:2016	Medical Devices - Quality Management Systems.
BS EN ISO 14971:2019	Medical devices - Application of Risk Management to Medical Devices.
BS EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. General requirements.
BS 7175:1989	Methods of test for the ignitability of bedcovers and pillows by smouldering and flaming ignition sources.
BS EN 597-1:2015	Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source smouldering cigarette.
BS EN 597-2:2015	Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source: match flame equivalent.
BS EN ISO 10993-1:2020	Biological evaluation of medical devices. Evaluation and testing.
BS EN ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity.
BS EN ISO 20342-1:2019	Assistive products for tissue integrity when lying down. General Requirements.