



EU Declaration of Conformity



repose[®]

Pressure Relief Devices & Accessories

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



Manufacturers Name:
Address:

Frontier Therapeutics Limited
Newbridge Road Industrial Estate,
Blackwood, Caerphilly
NP12 2YN. United Kingdom.
Tel: +44 (0) 330 460 6030
Email: info@frontier-group.co.uk
www.frontier-group.co.uk



Authorised Representative:
Address:

Frontier Therapeutics Limited
Geschäftsstelle Deutschland,
Nußbaumallee 27 A
14050 Berlin, Deutschland.
Tel: +49 3037026500
info@frontier-group.co.uk
www.frontier-medical-germany.de

This declaration of conformity is issued under the sole responsibility of Frontier Therapeutics Ltd. 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 (MD 74431). All supporting documentation is retained at the premises of the manufacturer.

For evaluation of the 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 Jackson**

Position/Title: **Chief Executive Officer**

Date: **21.05.2021**

Signature:

Product list

UDI-DI	Product Code (MPN)	Description	UDI-DI	Product Code (MPN)	Description
5056279301183YL	6020000	Repose Single Long Footprotector (Bagged)	5056279302227YN	651110401	Repose Protezione piede PLUS singolo x 10 e pompa
5056279301190YH	6020001	Repose Pair Long Footprotector (Bagged)	5056279302234YK	6511105	Repose Footprotector PLUS (Pair) x10 no pump
5056279301206Y7	6020002	Repose Single Footprotector and Pump (10 Pack)	5056279302241YG	6511106	Repose Footprotectors PLUS (Pair) and Pump (10 Pack)
5056279301213Y4	6020003	Repose Footprotectors (Pair) and Pump	5056279302258YZ	6511110	Repose Footprotector Plus (Pair) (Bulk Pack 10)
5056279301220XZ	6021000	Repose Single Long Footprotector and Pump	5056279302265YW	651111001	Repose Protezione piede PLUS coppia x 10 e pompa
5056279301237YJ	6021001	Repose Single Long Footprotector and Pump (10)	5056279302272YT	651111101	Repose Protezione piede PLUS coppia e pompa x 10
5056279301244YF	6021100	Repose Long Footprotectors (Pair) and Pump	5056279302289ZC	651111401	Repose Protezione piede PLUS singolo e pompa x 10
5056279301251YC	6021102	Repose Long Footprotectors (Pair) and Pump (Pack of 10)	5056279302296Z9	6520100	Repose Small Footprotector (Bulk Pack 10) with pump
5056279301992ZV	6500020	Repose Single Footprotector (Bagged)	5056279302302YB	6521100	Repose Small Footprotectors (Pair) and Pump
5056279302005Y2	6500100	Repose Footprotectors (Pair) (Bagged)	5056279302319YU	6521101	Repose Small Footprotectors (Pair) and Pump (10 Pack)
5056279302012XX	6500101	Repose Footprotectors (Pair) (Bagged) x 10 - no pump	5056279302326YR	6521102	Repose Small Footprotectors (Single) and Pump
5056279302029YG	6500200	Repose Footprotector (Pair) (Bulk Pack 10)	5056279302333YN	6521103	Repose Small Footprotectors (Pair) and Pump
5056279302036YD	6500201	Repose Long Footprotectors (Pair) (Bulk Pack 10)	5056279302340YK	6530100	Repose Extra Small Footprotector (Bulk Pack 10) with pump
5056279302043YA	6500202	Repose Footprotector (Pair) (Bulk Pack)	5056279302357Z4	6531100	Repose Extra Small Footprotectors (Pair) and Pump
5056279302050Y7	6501020	Repose Single Footprotector and Pump	5056279302364YZ	6531101	Repose Extra Small Footprotectors (Pair) and Pump (10 Pack)
5056279302067YQ	6501021	Repose Single Footprotector and Pump	5056279302371YW	6531102	Repose Extra Small Footprotectors (Single) and Pump
5056279302074YM	6501100	Repose Footprotectors (Pair) and Pump	5056279302388ZF	6531103	Repose Extra Small Footprotectors (Pair) and Pump
5056279302081YJ	650110001	Repose Protezione piede x2 e pompa	5056279302395ZC	6540100	Repose Small Footprotector Plus (Bulk Pack 10) with pump
5056279302098Z3	6501101	Repose Footprotectors (Pair) and Pump (10 Pack)	5056279302401YE	6541100	Repose Small Footprotectors Plus (Pair) and Pump
5056279302104Y5	6501102	Repose Footprotectors (Pair) and Pump	5056279302418YX	6541101	Repose Small Footprotectors Plus (Pair) and Pump (10 Pack)
5056279302111Y2	6501103	Repose Footprotector (10 Pr) and Pump	5056279302425YU	6541103	Repose Small Footprotectors Plus (Single) and Pump
5056279302128YK	6501104	Repose Footprotector (20 Pr) and Pump	5056279302432YR	6550100	Repose Extra Small Footprotector Plus (Bulk Pack 10) with pump
5056279302135YG	6501105	Repose Footprotector Lg(10S) and Pump	5056279302449ZA	6551100	Repose Extra Small Footprotectors Plus (Pair) and Pump
5056279302142YD	6501106	Repose Footprotector Lg (Pr) and Pump x	5056279302456Z7	6551101	Repose Extra Small Footprotectors Plus (Pair) and Pump (10 Pack)
5056279302159YW	6511100	Repose Footprotector PLUS (Pair) and pump	5056279302463Z4	6551103	Repose Extra Small Footprotectors Plus (Single) and Pump
5056279302166YT	651110001	Repose Protezione piede PLUS x2 e pompa	5056279302548ZD	6700100	Repose Wedge (Bagged)
5056279302173YQ	6511101	Repose Footprotector PLUS (Single) and pump	5056279302555ZA	6700101	Repose Wedge (Bulk Pack)

5056279302180YM	651110101	Repose Protezione piede PLUS singolo e pompa	5056279302562Z7	6700102	Repose Wedge (with Strap) (Bulk Pack 10)
5056279302197Z6	6511102	Repose Footprotector PLUS (Single) In Zip Bag	5056279302579ZQ	6710100	Repose Wedge (with Strap) (Bagged)
5056279302203Y8	6511103	Repose Footprotector PLUS (Pair) In Zip Bag	5056279302586ZM	6710101	Repose Wedge (with Strap) (Bagged) x 10
5056279302210Y5	6511104	Repose Single Footprotector PLUS and Pump	5056279302593ZJ	6711100	Repose Wedge (with Strap) and Pump
5056279302661ZA	6711114	Repose Wedge (With PU Strap) with Pump (10 Pack)	5056279302616Z5	6711101	Repose Wedge (with Strap) and Pump (10 Pack)
5056279302678ZT	6750000	Repose Flex - Extra Small 1 Flex and pump	5056279302623Z2	6711110	Repose Wedge (with PU Strap) Bagged
5056279302685ZQ	6750001	Repose Flex - Small 1 Flex and pump	5056279302630YX	6711111	Repose Wedge (with PU Strap) with pump
5056279302692ZM	6750002	Repose Flex - Standard 1 Flex and pump	5056279302647ZG	6711112	Repose Wedge (with PU Strap) x10 with small pump (Bulk Pack)
5056279302890ZT	6821100	Wedge - Large	5056279302654ZD	6711113	Repose Wedge (with PU Strap)x10 no Pump
5056279303224YP	6910100	Repose Wedge (50cm) (Bagged)	5056279303972Z8	7821100	Wedge - Large
5056279303231YL	6920100	Repose Wedge (50cm with Strap)	5056279303989ZR	7921100	Repose Wedge (50cm) and Pump 10 singles
5056279303248Z5	6921100	Repose Wedge (50cm) and Pump	5056279303996ZN	7921101	Repose Wedge (50cm 5 Tubes) and Pump 10 singles
5056279303255Z2	6921101	Wedge Without Strap - Large	5056279304009YQ	7930001	Repose Sole Protector and Pump 10 singles
5056279303262YX	6930000	Repose Sole Protector x 1 in zip lock bag	5056279304016YM	793000101	Repose Sole Protector e pompa 10 singloe
5056279303279ZG	6930001	Repose Sole Protector x 1 with Small Pump	5056279304153YY	675000001	Repose Flex - extra piccolo e pompa
5056279303286ZD	693000101	Repose Sole Protector x 1 e pumpa	5056279304160YV	675000101	Repose Flex - piccolo e pompa
5056279303293ZA	6930009	Repose Sole Protector bagged x 10 no Pump	5056279304177ZE	675000201	Repose Flex - standard e pompa
5056279303309YY	6930010	Repose Sole Protector x 10 with Small Pump	5056279304184ZB	760110001	TRAVERSA PER LETTIGHE E POMPA
5056279303514Z3	7501106	Repose Footprotector Lg (Pr) and Pump - 10 singles	5056279304191Z8	775000001	Repose Flex - extra piccolo e pompa
5056279303620Z3	7021000	Repose 1 Long Footprotector and pump 10 singles	5056279304207YW	775000101	Repose Flex - piccolo e pompa
5056279303637ZL	7021100	Repose Long Footprotectors (Pair) and Pump - 10 singles	5056279304214YT	775000201	Repose Flex - standard e pompa
5056279303781ZU	7501020	Repose Single Footprotector and Pump 10 singles	5056279304245Z6	6542000	Repose Foot Protector with Magnafix - Standard Size - 4 Layers (Pair)
5056279303798ZG	7501021	Repose Footprotectors and pumps - 10 singles	5056279304252Z3	6542001	Repose Foot Protector with Magnafix - Large Size - 4 Layers (Pair)
5056279303804ZF	7501100	Repose Footprotectors (Pair) and Pump - 10 singles	5056279304269ZL	6500300	4 Layer Standard Footprotector with Magnafix (Pair) (Bulk Pack 10)
5056279303811ZC	7501102	Repose Footprotector (Pairs) and Pumps - 10 singles	5056279304276ZH	6500301	4 Layer Large Footprotector with Magnafix (Pair) (Bulk Pack 10)
5056279303828ZV	7501106	Repose Footprotector Lg (Pr) and Pump - 10 singles	5056279304306YZ	7542000	4 Layer Footprotector with Magnafix (Pair) - Standard Size
5056279303835ZS	7511100	Repose Footprotector PLUS (Pair) and pump - 10 singles	5056279304313YW	7542001	4 Layer Footprotector with Magnafix (Pair) - Large Size
5056279303842ZP	7511101	Repose Footprotector plus (Singles) and pump - 10 singles	5056279304610Z7	7750002	Repose Flex - Standard (1 Flex and pump)
5056279303859ZB	751110101	Repose Protezione piede PLUS singolo e pompa - 10 singole	5056279304627ZQ	7521100	Small Foot Protector (pair) and pump
5056279303897ZK	7701100	Repose Wedge and Pump 10 singles	5056279304634ZM	6750000	Repose Flex - Extra Small
5056279303903ZJ	7711100	Repose Wedge (with Strap) and Pump 10 singles	5056279304641ZJ	6750010	Repose Flex - Extra Small

5056279303910ZF	771110001	Repose Cuscino di sostegno 10 single	505627930465826	6750110	Repose Flex - Extra Small
50562793046962E	6750111	Repose Flex - Small	505627930466523	6750210	Repose Flex - Extra Small
5056279304702ZD	6750211	Repose Flex - Small	5056279304672ZV	6750001	Repose Flex - Small
5056279304719ZW	6750002	Repose Flex - Standard	50562793046892H	6750011	Repose Flex - Small
5056279304726ZT	6750012	Repose Flex - Standard	5056279305242Z7	6921001	Wedge Without Strap - Large
5056279304733ZQ	6750112	Repose Flex - Standard	5056279305259ZQ	6921010	Wedge Without Strap - Large
5056279304740ZM	6750212	Repose Flex - Standard	5056279305266ZM	6921011	Wedge Without Strap - Large
50562793047952H	7750000	Repose Flex - Extra Small	5056279305273ZJ	7921011	Wedge Without Strap - Large
5056279304801ZG	7750001	Repose Flex - Small	5056279305297Z3	6921110	Wedge Without Strap - Large
505627930481824	7750002	Repose Flex - Standard	5056279305747ZD	6922001	Repose® Wedge Without Strap Large x1
5056279304825ZW	6260001	Repose Foot Protector Lite Standard	5056279305754Z2A	6922011	Repose® Wedge Without Strap Large x1 & Pump x1
505627930487026	6711115	Wedge with Extra Long TPU Strap	5056279305761Z7	6922101	Repose® Wedge Without Strap Large x10 & Pump x10
50562793048872P	6711116	Wedge with Extra Long TPU Strap	5056279305198ZV	6821010	Wedge - Large
50562793048942L	6711117	Wedge with Extra Long TPU Strap	5056279305228ZD	6821110	Wedge - Large
5056279304900ZK	6711118	Wedge with Extra Long TPU Strap	5056279305235Z2A	6821011	Wedge - Large
5056279305181ZC	6821001	Wedge - Large			

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 14971:2012	Medical devices - Application of risk management to medical devices.
BS EN 1041:2008	Information supplied by the manufacturer of medical devices.
BS EN ISO 15223-1:2016	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. (Ignitability resistance to Sources 0, 1 & 5.)
BS 5852:2006	Methods of test for assessment of the ignitability of upholstered seating by smouldering and flaming ignition sources.
BS 6807:2006	Methods of test for assessment of ignitability of mattresses, upholstered divans and upholstered bed bases with flaming types of primary and secondary sources of ignition.
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 1728:2012	Furniture – Seating – Test methods for the determination of strength & durability.
BS EN ISO 10993-1:2009	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 10993-12:2012	Biological evaluation of medical devices. Sample preparation and reference materials
BS EN 1957:2012	Furniture. Beds and mattresses. Test methods for the determination of functional characteristics and assessment criteria.
BS EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
BS EN ISO 20342-1:2019	Assistive products for tissue integrity when lying down. General Requirements






EU Declaration - Repose_Footcare_Solutions_I1

Final Audit Report

2021-05-22

Created:	2021-05-22
By:	Simon Bosley (sbosley@frontier-group.co.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAWc0rhCiPoCT53sAidDIpMn3RwyE7G5y

"EU Declaration - Repose_Footcare_Solutions_I1" History

-  Document created by Simon Bosley (sbosley@frontier-group.co.uk)
2021-05-22 - 6:30:41 AM GMT- IP address: 185.69.144.11
-  Document emailed to Simon Jackson (sjackson@frontier-group.co.uk) for signature
2021-05-22 - 6:31:03 AM GMT
-  Email viewed by Simon Jackson (sjackson@frontier-group.co.uk)
2021-05-22 - 11:03:51 AM GMT- IP address: 104.47.20.254
-  Document e-signed by Simon Jackson (sjackson@frontier-group.co.uk)
Signature Date: 2021-05-22 - 11:04:35 AM GMT - Time Source: server- IP address: 86.163.1.226
-  Agreement completed.
2021-05-22 - 11:04:35 AM GMT