



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 Codes (MPN)	Description	UDI-DI	Product Codes (MPN)	Description
5056279300865ZE	6211100	Repose Repose Blue Cushion Cover UK 45 cm	5056377401855ZL	6310001	Repose Contur with 1 Contur Cover and pump
5056279300872ZB	621110001	Repose Blu Cover Cuscino 45cm Blue Cushion Cover	5056377401862ZH	631000101	CONTUR REPOSE 1 COPERTURA PER CONTUR
5056279300889ZU	6211101	Repose Blue Cushion Cover EU 45 cm	505637740187925	6310002	Repose Contur with 2 Contur Covers and pump
5056279300896ZR	6211102	Repose Blue Cushion Cover EU 40 cm	505637740188622	631000201	CONTUR REPOSE 2 COPERTURE PER CONTUR
5056377400933Z8	6300000	Repose Contur Cover	5056377401893ZU	6350001	Repose Care-Sit 40 cm with 1 Cover and pump
5056377400940Z5	6310000	Repose Contur Cover - UK	5056377401909ZJ	635000101	Repose Care - sit e fodera 40
5056377400957ZN	6311000	Repose Contur Cover - RoW	5056377401916ZF	6350011	Repose Care-Sit 40 cm
5056377400964ZK	6350000	Repose Care-Sit Cover - 40 cm	5056377401923ZC	6351001	Repose Care-Sit 45 cm with 1 Cover and pump
5056377400971ZG	6351000	Repose Care-Sit Cover - 45 cm	5056377401930Z9	635100101	Repose Care - sit e fodera 45
5056279301121XW	6000001	Repose Cushion Extension strap	5056377401947Z5	6351011	Repose Care-Sit 45 cm No Cover and pump
5056377401138YH	6000002	Repose Care-Sit / Contur Ext. strap	5056279302609Z8	671110001	Repose Cuscino di sostegno
5056279301145YC	6010101	Repose Cushion Repair Kit (TIPS)	5056279303743ZL	7201100	Repose Cushion and Pump 10
5056279301268YV	6040100	Repose Cushion Repair Pack	5056279303750ZH	720110001	Repose Cuscino e pompa 10 singole
5056279301442YM	6121100	Repose Mattress Cushion	5056279303767Z5	7201102	Repose Cushion (40 cm) and Pump
5056279301459Z6	612110001	Repose Traversa Cuscino e pompa	5056279304146Z3	6201105	Repose Cushion Bundle Pack
5056279301596ZH	6200100	Repose Cushion (Bagged)	5056377405402Z7	6360001	Care-Sit High Back
5056279301602YK	6200101	Repose Cushion (Bulk Pack 10)	5056377405419ZQ	6360011	Care-Sit High Back
5056279301619Z4	6200102	Repose Cushion (Bulk Pack 25)	5056377405426ZM	6361010	Care-Sit High Back
5056279301626YZ	6200103	Repose Cushion (Bagged) x 10	5056377405433ZJ	6361100	Care-Sit High Back
5056279301633YW	6201100	Repose Cushion and Pump	5056377405440ZF	6320001	Contur Short
5056279301640YT	620110001	Repose Cuscino e pompa	5056377405457Z3	6320011	Contur Short
5056279301657ZC	620110011	Repose Cuscino x 10 e pompa	5056377405464ZV	6321010	Contur Short
5056279301664Z9	6201101	Repose Cushion and Pump (10 Pack)	5056377405471Z5	6321100	Contur Short
5056279301671Z6	620110101	Repose Cuscino e pompa x 10	5056279305525ZN	6211103	Repose Cushion Cover UK 45cm
5056279301688ZP	6201102	Repose Cushion (40 cm) and Pump	5056377405563Z3	6330001	Contur
5056279301695ZL	6201103	Repose Cushion and Pump	5056377405570ZV	6330011	Contur
5056279301701YN	6201104	Repose Cushion Pump Blue cover with extension strap	5056377405587Z2H	6331010	Contur
5056279301718Z7	6231100	Repose 45 cm Cushion Pump and PU Cover UK	5056377405594ZE	6331100	Contur
5056279301725Z4	6231101	Repose Cushion Small Pump and 2 Covers	5056377405600ZD	6340001	Contur Long
5056279301732YZ	6231102	Repose 45 cm Cushion Small Pump and 1 Cover	5056377405617ZW	6340011	Contur Long
5056279301749ZJ	6231104	Repose Refresh Cushion Cover 45cm	5056377405624ZT	6341010	Contur Long
5056279301756ZF	6231105	Repose Refresh Cushion Cover 40cm	5056377405631ZQ	6341100	Contur Long
5056279301763ZC	6231110	Repose 45 cm Cushion Pump and PU Cover EU	5056377401848ZP	6300004	Repose Contur Overlay bagged
5056377401787ZU	6300001	Repose Contur with 1 Contur Cover	5056377401831Z6	630000301	Repose CONTUR REPOSE
5056377401794ZR	630000101	Repose Materasso di rivestimento	5056377401817ZC	630000201	Repose Materasso di rivestimento
5056377401800YT	6300002	Repose Contur with 2 Contur	5056377401824Z9	6300003	Repose Contur overlay and pump
5056279301770Z9	6250010	Repose Lite Cushion - 10 Pack	5056279304771Z3	6251010	Repose Cushion Lite - x10 w Cover
5056279304320YT	6251000	Repose Lite Cushion w Cover - UK	5056279304337ZC	6250001	Repose Lite Cushion

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_Seating_Solutions_I1

Final Audit Report

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