



EU Declaration of Conformity



Pressure Relief Devices & Accessories

Repose Basic-UDI = 50562793ReposeGN
(See Appendix 1 & 2 for product list, codes and applicable UDI-DI)

Intended Purpose*

Repose® Class I medical devices are a range of reactive air, pressure redistribution and reduction support surfaces, intended for individuals at risk of developing pressure ulcers, including those at very high risk, and for the treatment of all categories or stages of pressure ulcers when used as part of a package of care.

* This is consistent with Intended Purpose Document, Version 02, INP-DP0342-001



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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 Appendices 1 & 2 conform to the requirements of **Regulation (EU) 2017/745** on medical devices, in particular **Article 10(6), Article 19, and Annex IV**.

This declaration is supported by the Quality Management System certified to **ISO 13485:2016** by **BSI Group** (Certificate Number: MD **74431**). All supporting documentation is retained at the manufacturer's premises.

For the evaluation of compliance with this Regulation, the harmonised standards listed in **Appendices 3, 4 & 5** have been applied as specified..

Risk Class: Medical device, Class I

Person responsible for making the declaration:

Name, Surname: **Jim Yang**

Position/Title: **Chief Technical Officer**

Date: **25-Jul-2025**

Signature:

Place of Issue: **Frontier Therapeutics Limited**
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Appendix 1.

Product List: Repose® and Repose® Covers.

Description	Product Codes (MPN)	UDI-DI
Repose Cushion Extension strap	6000001	5056279301121
Repose Care-Sit / Contur Extension strap	6000002	5056279301138
Repose Cushion Repair Kit (TIPS)	6010101	5056279301145
Repose Cushion Repair Pack	6040100	5056279301268
Repose Cushion (Bagged)	6200100	5056279301596
Repose Cushion (Bulk Pack 10)	6200101	5056279301602
Repose Cushion (Bulk Pack 25)	6200102	5056279301619
Repose Cushion (Bagged) x 10	6200103	5056279301626
Repose Cushion and Pump	6201100	5056279301633
Repose Cushion and Pump (10 Pack)	6201101	5056279301664
Repose Cushion (40 cm) and Pump	6201102	5056279301688
Repose Cushion and Pump USA	6201103	5056279301695
Repose Cushion Pump Blue cover with extension strap	6201104	5056279301701
Repose Cushion Bundle Pack - 10 Cushions - 10 Covers - 1 Small Pump	6201105	5056279304146
Repose Repose Blue Cushion Cover UK 45cm	6211100	5056279300865
Repose Blue Cushion Cover EU 45cm	6211101	5056279300889
Repose Blue Cushion Cover EU 40cm	6211102	5056279300896
Repose Cushion Cover UK 45cm	6211103	5056279305525
Repose 45cm Cushion Pump and PU CoverUK	6231100	5056279301718
Repose Cushion Small Pump and 2 Covers	6231101	5056279301725
Repose 45 cm Cushion Small Pump and 1Cover	6231102	5056279301732
Repose Refresh Cushion Cover 45cm	6231104	5056279301749
Repose Refresh Cushion Cover 40cm	6231105	5056279301756
Repose 45cm Cushion Pump and PU CoverEU	6231110	5056279301763
Repose Lite Cushion	6250001	5056279304337
Repose Lite Cushion - 10 Pack	6250010	5056279301770
Repose Lite Cushion w Cover - UK	6251000	5056279304320
Repose Cushion Lite - x10 w Cover	6251010	5056279304771
Repose Contur Cover	6300000	5056377400933
Repose Contur with 1 Contur Cover	6300001	5056377401787
Repose Contur with 2 Contur	6300002	5056377401800
Repose Contur overlay and pump	6300003	5056377401824
Repose Contur Overlay bagged	6300004	5056377401848
Repose Contur Overlay bagged	6300004	5056279301848
Repose Contur Cover - UK	6310000	5056279300940
Repose Contur with 1 Contur Cover andpump	6310001	5056377401855
Repose Contur with 2 Contur Covers andpump	6310002	5056377401879
Repose® Contur Overlay x4 & Cover x4 & Pump x4 (4 pack of 6310001)	6310003	5056279307833
Repose Contur Cover - Rest of the World	6311000	5056279300957
Contur Short x 1 (Bagged)	6320001	5056279305440
Contur Short x 1 & Pump x 1	6320011	5056279305457
Contur Short x 10 & Pump x 10 (Bulk Pack)	6321010	5056279305464
Contur Short x 10 & Pump x 1 (Bulk Pack)	6321100	5056279305471
Contur x 1 (Bagged)	6330001	5056279305563
Contur x 1 & Pump x 1	6330011	5056279305570
Contur x 10 & Pump x 10 (Bulk Pack)	6331010	5056279305587
Contur x 10 & Pump x 1 (Bulk Pack)	6331100	5056279305594
Contur Long x 1 (Bagged)	6340001	5056279305600
Contur Long x 1 & Pump x 1	6340011	5056279305617
Contur Long x 10 & Pump x 10 (Bulk Pack)	6341010	5056279305624
Contur Long x 10 & Pump x 1 (Bulk Pack)	6341100	5056279305631
Repose Care-Sit Cover - 40 cm	6350000	5056279300964
Repose Care-Sit 40 cm with 1 Cover and pump	6350001	5056279301893
Repose Care-Sit 40 cm No Cover and pump	6350011	5056279301916
Repose Care-Sit Cover - 45 cm	6351000	5056279300971
Repose Care-Sit 45 cm with 1 Cover and pump	6351001	5056279301923
Care-Sit 45 cm No Cover and pump	6351011	5056279301947
Care-Sit High Back x 1 (Bagged)	6360001	5056279305402
Care-Sit High Back x 1 & Pump x 1	6360011	5056279305419

Care-Sit High Back x 10 & Pump x 10 (Bulk Pack)	6361010	5056279305426
Care-Sit High Back x 10 & Pump x 1 (Bulk Pack)	6361100	5056279305433
Repose Cushion and Pump 10 singles	7201100	5056279303743
Repose Cushion (40 cm) and Pump 10 singles	7201102	5056279303767
Repose Traversa Cuscino e pompa	612110001	5056279301459
Repose Cuscino e pompa	620110001	5056279301640
Repose Cuscino x 10 e pompa	620110011	5056279301657
Repose Cuscino e pompa x 10	620110101	5056279301671
Repose Blu Cover Cuscino 45cm Blue Cushion Cover	621110001	5056279300872
Repose Materasso di rivestimento	630000101	5056377401794
Repose Materasso di rivestimento	630000201	5056377401817
Repose CONTUR REPOSE E POMPA	630000301	5056279301831
Repose CONTUR REPOSE 1 COPERTURA PER CONTUR+ POMPA	631000101	5056279301862
Repose CONTUR REPOSE 2 COPERTURE PER CONTUR E POMPA	631000201	5056279301886
Repose Care - sit e fodera 40 cm	635000101	5056279301909
Repose Care - sit e fodera 45 cm	635100101	5056279301930
Repose Cuscino di sostegno	671110001	5056279302609
Repose Cuscino e pompa 10 singole	720110001	5056279303750

Note – This includes all derivatives/variants and sizes of the above-stated products.

Appendix 2.

Product List: Repose® and Enora® Covers.

Description	Product Codes	UDI-DI
enora® Air Cushion x1 (45cm) & Cover x1 (Uplifting Blue) & Air Pump (Small) x1	8002000	5056279307123
enora® Air Cushion (45cm) x1 & Cover x1 (Glowing Green) & Air Pump (Small) x1	8002001	5056279307246
enora® Air Cushion (45cm) x1 & Cover x1 (Relieving Peach) & Air Pump (Small) x1	8002002	5056279307369
enora® Air Cushion (45cm) x1 & Cover x1 (Luminous Yellow) & Air Pump (Small) x1	8002003	5056279307482
enora® Air Cushion x1 (45cm) & Cover x2 (Uplifting Blue) & Air Pump (Small) x1	8002010	5056279307130
enora® Air Cushion (45cm) x1 & Cover x2 (Glowing Green) & Air Pump (Small) x1	8002011	5056279307253
enora® Air Cushion (45cm) x1 & Cover x2 (Relieving Peach) & Air Pump (Small) x1	8002012	5056279307376
enora® Air Cushion (45cm) x1 & Cover x2 (Luminous Yellow) & Air Pump (Small) x1	8002013	5056279307499
enora® Air Cushion x2 (45cm) & Cover x2 (Uplifting Blue) & Air Pump (Small) x1	8002020	5056279307147
enora® Air Cushion (45cm) x2 & Cover x2 (Glowing Green) & Air Pump (Small) x1	8002021	5056279307260
enora® Air Cushion (45cm) x2 & Cover x2 (Relieving Peach) & Air Pump (Small) x1	8002022	5056279307383
enora® Air Cushion (45cm) x2 & Cover x2 (Luminous Yellow) & Air Pump (Small) x1	8002023	5056279307505
enora® Air Cushion Cover x1 (45cm) (Uplifting Blue)	8002030	5056279306966
enora® Air Cushion Cover x1 (45cm) (Glowing Green)	8002031	5056279306973
enora® Air Cushion Cover x1 (45cm) (Relieving Peach)	8002032	5056279306980
enora® Air Cushion Cover x1 (45cm) (Luminous Yellow)	8002033	5056279306997
enora® Air Cushion (45cm) Complete Single Product x1	8002050	5056279307604
enora® Air Cushion x1 (45cm) & Cover x1 (Uplifting Blue)	8002100	5056279307949
enora® Air Cushion x1 (45cm) & Cover x1 (Glowing Green)	8002101	5056279307956
enora® Air Cushion x1 (45cm) & Cover x1 (Relieving Peach)	8002102	5056279307963
enora® Air Cushion x1 (45cm) & Cover x1 (Luminous Yellow)	8002103	5056279307970
enora® Air Contur x1 & Cover x1 (Uplifting Blue) & Air Pump (Large) x1	8003000	5056279307154
enora® Air Contur x1 & Cover x1 (Glowing Green) & Air Pump (Large) x1	8003001	5056279307277
enora® Air Contur x1 & Cover x1 (Relieving Peach) & Air Pump (Large) x1	8003002	5056279307390
enora® Air Contur x1 & Cover x1 (Luminous Yellow) & Air Pump (Large) x1	8003003	5056279307512
enora® Air Contur x1 & Cover x2 (Uplifting Blue) & Air Pump (Large) x1	8003010	5056279307161
enora® Air Contur x1 & Cover x2 (Glowing Green) & Air Pump (Large) x1	8003011	5056279307284
enora® Air Contur x1 & Cover x2 (Relieving Peach) & Air Pump (Large) x1	8003012	5056279307406
enora® Air Contur x1 & Cover x2 (Luminous Yellow) & Air Pump (Large) x1	8003013	5056279307529
enora® Air Contur Cover x1 (Uplifting Blue)	8003030	5056279307000
enora® Air Contur Cover x1 (Glowing Green)	8003031	5056279307017
enora® Air Contur Cover x1 (Relieving Peach)	8003032	5056279307024
enora® Air Contur Cover x1 (Luminous Yellow)	8003033	5056279307031
enora® Air Contur Complete Single Product x1	8003050	5056279307611
enora® Air Contur x1 & Cover x1 (Uplifting Blue)	8003100	5056279307987
enora® Air Contur x1 & Cover x1 (Glowing Green)	8003101	5056279307994
enora® Air Contur x1 & Cover x1 (Relieving Peach)	8003102	5056279308007
enora® Air Contur x1 & Cover x1 (Luminous Yellow)	8003103	5056279308014
enora® Air Seat x1 & Cover x1 (45cm) (Uplifting Blue) & Air Pump (Small) x1	8005000	5056279307222
enora® Air Seat (45cm) x1 & Cover x1 (Glowing Green) & Air Pump (Small) x1	8005001	5056279307345
enora® Air Seat (45cm) x1 & Cover x1 (Relieving Peach) & Air Pump (Small) x1	8005002	5056279307468
enora® Air Seat (45cm) x1 & Cover x1 (Luminous Yellow) & Air Pump (Small) x1	8005003	5056279307581
enora® Air Seat x1 & Cover x2 (45cm) (Uplifting Blue) & Air Pump (Small) x1	8005010	5056279307239

enora® Air Seat (45cm) x1 & Cover x2 (Glowing Green) & Air Pump (Small) x1	8005011	5056279307352
enora® Air Seat (45cm) x1 & Cover x2 (Relieving Peach) & Air Pump (Small) x1	8005012	5056279307475
enora® Air Seat (45cm) x1 & Cover x2 (Luminous Yellow) & Air Pump (Small) x1	8005013	5056279307598
enora® Air Seat Cover x1 (45cm) (Uplifting Blue)	8005030	5056279307086
enora® Air Seat Cover x1 (45cm) (Glowing Green)	8005031	5056279307093
enora® Air Seat Cover x1 (45cm) (Relieving Peach)	8005032	5056279307109
enora® Air Seat Cover x1 (45cm) (Luminous Yellow)	8005033	5056279307116
enora® Air Seat (45cm) Complete Single Product x1	8005050	5056279307635
enora® Air Seat Strap Extenders x2	8005074	5056279307895
enora® Air Seat (45cm) x1 & Cover x1 (Uplifting Blue)	8005100	5056279308069
enora® Air Seat (45cm) x1 & Cover x1 (Glowing Green)	8005101	5056279308076
enora® Air Seat (45cm) x1 & Cover x1 (Relieving Peach)	8005102	5056279308083
enora® Air Seat (45cm) x1 & Cover x1 (Luminous Yellow)	8005103	5056279308090
enora® Air Cushion x1 (45cm) & Cover x1 (Uplifting Blue) & Air Pump (Small) x1	8020000	5056279308106
enora® Air Cushion x1 (45cm) & Cover x1 (Glowing Green) & Air Pump (Small) x1	8020001	5056279308113
enora® Air Cushion x1 (45cm) & Cover x1 (Relieving Peach) & Air Pump (Small) x1	8020002	5056279308120
enora® Air Cushion x1 (45cm) & Cover x1 (Luminous Yellow) & Air Pump (Small) x1	8020003	5056279308137
enora® Air Contur x1 & Cover x1 (Uplifting Blue) & Air Pump (Small) x1	8030000	5056279308144
enora® Air Contur x1 & Cover x1 (Glowing Green) & Air Pump (Small) x1	8030001	5056279308151
enora® Air Contur x1 & Cover x1 (Relieving Peach) & Air Pump (Small) x1	8030002	5056279308168
enora® Air Contur x1 & Cover x1 (Luminous Yellow) & Air Pump (Small) x1	8030003	5056279308175
enora® Air Seat (45cm) x1 & Cover x1 (Uplifting Blue) & Air Pump (Small) x1	8050000	5056279308229
enora® Air Seat (45cm) x1 & Cover x1 (Glowing Green) & Air Pump (Small) x1	8050001	5056279308236
enora® Air Seat (45cm) x1 & Cover x1 (Relieving Peach) & Air Pump (Small) x1	8050002	5056279308243
enora® Air Seat (45cm) x1 & Cover x1 (Luminous Yellow) & Air Pump (Small) x1	8050003	5056279308250
Note – This includes all derivatives/variants and sizes of the above-stated products.		

Appendix 3.

All Common Applicable Standards.

Standard Description	Standard
Medical devices – Quality Management Systems	BS EN ISO 13485:2016+A11:2021
Medical devices-Application of Risk management to medical devices	BS EN ISO 14971:2019+A11:2021
Medical devices; Part 1: Application of usability engineering to medical devices	BS EN 62366-1:2015+A1:2020
Biological evaluation of medical devices, Part 1: Evaluation and testing with a risk management process	BS EN ISO 10993-1:2020
Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity	BS EN ISO 10993-5:2009+A11:2025
Biological evaluation of medical devices, Part 10: Tests for skin sensitization	BS EN ISO 10993-10:2023
Biological evaluation of medical devices, Part 23: Tests for irritation	BS EN ISO 10993-23:2021
Biological evaluation of medical devices, Part 12: Sample preparation and reference materials	BS EN ISO 10993-12:2021
Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements	BS EN ISO 15223-1:2021
Medical devices. Information to be supplied by the manufacturer	BS EN ISO 20417:2021

Note - Both Repose and Enora are branded products that utilise the same underlying medical device technology – specifically the inflatable ‘inner’. Therefore the standards listed above are applicable for both Repose and Enora products stated within this document.

Appendix 4.

All Applicable Standards: Repose® Covers.

Description	Standard
Methods of test for the ignitability of bedcovers and pillows by smouldering and flaming ignition sources.	BS 7175:1989 (UK Covers Only)
Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source smouldering cigarette.	BS EN 597-1:2015
Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source: match flame equivalent.	BS EN 597-2:2015

Note – The standards listed above are applicable for Repose product ranges ONLY stated within this document

Appendix 5.

All Applicable Standards: Enora® Covers.

Description	Standard
Specification For Resistance to Ignition of Mattresses, Mattress Pads, Divans, and Bed Bases	BS 7177 - Low Hazard (Sources 0 & 1)
Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source smouldering cigarette	BS EN 597-1:2015
Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source: match flame equivalent	BS EN 597-2:2015

Standards for the Flammability of Mattresses and Mattress Pads	16 CFR part 1632
Requirements, Test Procedure and Apparatus for testing the Smoulder Resistance of Materials Used in Upholstered Furniture	California TB117-2013
Note – The standards listed above are applicable for <i>enora</i> product ranges ONLY stated within this document	






EU Declaration - Repose Seating Solutions - I10

Final Audit Report

2025-07-25

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"EU Declaration - Repose Seating Solutions - I10" History

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