



# EU Declaration of Conformity



## Pressure Relief Devices & Accessories

Repose Basic-UDI = 50562793ReposeGN

(See Appendix 1, 2 & 3 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



Manufacturers Name:  
Address:  
**SRN – GB-MF-000035429**

**Frontier Therapeutics Limited**  
Innova One, Tredgar Business Park,  
Tredgar, Blaenau Gwent,  
NP22 3EL. United Kingdom.  
Tel: +44 (0) 330 460 6030  
Email: info@frontier-group.co.uk  
www.frontier-group.co.uk



Authorised Representative:  
Address:  
**Importer SRN – DE-IM-000031640**  
**EU Rep SRN – DE-AR-000031721**

**Frontier Medical Germany GmbH**  
Kolonnenstr. 8,  
10827, Berlin. Deutschland.  
Tel: +49 (0) 305 200 6046  
Email: info@frontier-group.co.uk  
www.frontier-medical-germany.de

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, and 3 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 4, 5, and 6** 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: **24-Jul-2025**

Signature:

Place of Issue: **Frontier Therapeutics Limited**  
Innova One, Tredgar Business Park,  
Tredgar, Blaenau Gwent,  
NP22 3EL. United Kingdom.

**Appendix 1.**

**Product List: Repose® and Repose® Covers.**

Description	Product Codes (MPN)	UDI-DI
Mattress Overlay Extension Strap - TPU	6000003	5056279304856
Repose Long Mattress and Pump	6011100	5056279301152
Repose Long Mattress and Pump (10 Pack)	6011101	5056279301169
Repose Long Mattress and Pump USA (6 Pack)	6011102	5056279301176
Repose Mattress Overlay Long and Cover (No Pump)	6011103	5056279305501
Refresh Mattress Cover	6050101	5056279301299
Mattress Repair Kit (TIPS)	6050102	5056279301305
Mattress Overlay Refresh Cover	6050111	5056279304757
Mattress Overlay Refresh Cover with Extra Long TPU Strap	6050113	5056279304924
Mattress Overlay Refresh Cover with Extra Long TPU Strap	6050114	5056279304931
Repose Standard Mattress (Bagged)	6100100	5056279301312
Repose Standard Mattress (Bagged) x 10	6100101	5056279301329
Repose Short Mattress In Zip Lock Bag	6100105	5056279301336
Mattress Overlay with Extra Long TPU Straps	6100110	5056279305013
Mattress Overlay with Extra Long TPU Straps	6100111	5056279305020
Mattress Overlay with Extra Long TPU Straps	6100112	5056279305037
Mattress Overlay with Extra Long TPU Straps	6100113	5056279305044
Mattress Overlay with Extra Long TPU Straps	6100114	5056279305051
Mattress Overlay with TPU Straps	6100115	5056279305068
Mattress Overlay with TPU Straps	6100116	5056279305075
Mattress Overlay with TPU Straps	6100117	5056279305082
Mattress Overlay with TPU Straps	6100118	5056279305099
Mattress Overlay with TPU Straps	6100119	505627930510
Repose Mattress (60 x 80cm) (Bagged)	6101000	5056279301343
Repose Mattress and Pump	6101100	5056279301350
Repose Mattress (120 x 65cm) and Pump	6101101	5056279301374
Repose Mattress and Pump (10 Pack)	6101102	5056279301381
Repose Mattress and Pump with PU Cover UK	6101110	5056279301404
Repose Mattress and Pump with PU Cover EU	6101111	5056279301411
Repose Long Mattress and Pump with PU Cover International	6101120	5056279304788
Repose Long Mattress and Pump (Bulk Pack 10)	6111100	5056279301428
Repose Mattress and Pump (Bulk Pack)	6111101	5056279301435
Repose Mattress Cushion	6121100	5056279301442
Repose Long Mattress	6121101	5056279301466
Repose Mattress Cushion and Pump (10 Pack)	6121102	5056279301473
Repose Long Mattress Cushion and Pump (10 Pack)	6121103	5056279301480
Repose Double Mattress and small pump	6131100	5056279301497
Repose Double Mattress	6131101	5056279301510
Repose® Double Mattress Overlay x4 & Pump x4 (4 pack of 6131100)	6131102	5056279307857
Prone Mattress Overlay	6141001	5056279305129
Prone Mattress Overlay	6141010	5056279305136
Prone Mattress Overlay	6141100	5056279305143
Prone Mattress Overlay	6141101	5056279305174
Prone Mattress Overlay	6141110	5056279305167
Prone Kit	6170101	5056279305303
Prone Kit with Pump	6170102	5056279305327
Prone Kit	6170110	5056279305310
Prone Kit	6170111	5056279305358
Prone Kit	6170112	5056279305341
Repose Long Mattress (Bagged)	6180100	5056279301527
Repose Mattress (70 x 45 cm) and Pump	6180102	5056279301534
Repose Mattress (38 x 72cm) and Pump	6181100	5056279301541
Repose Mattress (74 x 54cm) and Pump	6181103	5056279301558
Repose Mattress (140 x 70cm) and Pump	6181104	5056279301565
Repose Mattress (75 x 43cm) and Pump	6181105	5056279301572
Repose Mattress (89 x 45cm) and Pump	6181106	5056279301589
Repose Blue Mattress Cover UK	6211110	5056279300902
Repose Blue Mattress Cover EU	6211111	5056279300919
Repose Long Mattress Cover EU	6211112	5056279300926
Repose Mattress Overlay Lite for Ultracore - Single	6270001	5056279304849

Repose Pump (Long)	6801000	5056279302722
Repose Pump (Long) REPROCESSED Carton of 10	6801001	5056279302746
Repose Pump (Long) x10	6801010	5056279302753
Repose Pump (Short) x10	6801011	5056279302777
Repose Small Pump	6802000	5056279302869
Repose Pump (Small) REPROCESSED Carton of 10 of 10	6802001	5056279302883
Ultracore Pump	6803000	5056279305372
Ultracore Pump	6803010	5056279305396
Repose Repose Mattress Overlay Cover	6980002	5056279303316
Repose Inbo Mattress	6990100	5056279303415
Repose INBO mattress and Pump	6990110	5056279303422
Repose INBO Mattress and Pump (10 Pac k)	6990111	5056279303439
Repose INBO mattress (70 cm) and Pump	6990112	5056279303446
Repose Mattress (60 x 80cm) and Pump	6991100	5056279303460
Repose Long Mattress and Pump 10 singles	7011100	5056279303613
Repose Mattress and Pump 10 singles	7101100	5056279303644
Repose Mattress (120 x 65cm) and Pump 10 singles	7101101	5056279303507
Repose Mattress Cushion and Pump 10 singles	7121100	5056279303675
Prone Mattress Overlay	7141100	5056279305150
Prone Kit	7170102	5056279305334
Repose Mattress (70 x 45 cm) and Pump 10 singles	7180102	5056279303699
Repose Mattress (74 x 54cm) and Pump 10 singles	7181103	5056279303712
Repose Mattress (140 x 70cm) and Pump 10 singles	7181104	5056279303729
Repose Mattress (75 x 43 cm) and Pump 10 singles	7181105	5056279303736
Repose Pump (Long) 10 singles	7801000	5056279303927
Repose Small Pump 10 singles	7802000	5056279303965
Ultracore Pump	7803000	5056279305389
Repose INBO mattress and Pump 10 singles	7990110	5056279304023
Repose INBO mattress (70 cm) and Pump 10 singles	7990112	5056279304030
Repose Mattress (60 x 80cm) and Pump 10 singles	7991100	5056279303552
Repose Ultracore Cover	9000001	5056279301084
Repose Ultracore Cover	9000001	5056279301084
Repose Ultracore EXPORT Cover	9000002	5056279301091
Repose Ultracore EXPORT Cover	9000002	5056279301091
Repose Ultracore Inner / Overlay	9000020	5056279303569
Repose Ultracore	9100011	5056279303576
Repose Ultracore Plus	9100012	5056279303583
Repose Ultracore EXPORT	9100013	5056279303590
Repose Ultracore Plus EXPORT	9100014	5056279303606
Ultracore® Repose® Lite Inside - Cover	9200001	5056279305365
Ultracore Repose® Lite Inside	9200010	5056279304917
Repose Materasso di rivestimento e pompa x 1	630000101	5056279301794
Repose Materasso di rivestimento e pompa x 2	630000201	5056279301817
Repose POMPA (grande)	680100001	5056279302739
Repose POMPA (grande) x10	680101001	5056279302760
Repose POMPA (piccola) x10	680101101	5056279302784
Repose POMPA PICCOLA	680200001	5056279302876
Repose SET DA TRASPORTO MATERASSO E POMPA	699000301	5056377403330
Repose SET DA TRASPORTO MATERASSO E POMPA - DUE PEZZ	699000401	5056377403354
<b>Note – This includes all variants and sizes of the above-stated products.</b>		

## Appendix 2.

### Product List: Repose® Paediatric.

Description	Product Codes (MPN)	UDI-DI
Repose Paediatric Mattress (750mm x 430mm) Complete single product	079010	5056279300315
Repose Paediatric Mattress Complete single product	079017	5056279300384
Repose Baby Therm (760mm x 530mm) Complete single product	079021	5056279300421
Repose Baby nest Complete single product	079023	5056279300438
Repose Baby nest - without rim Complete single product	079040	5056279300599
Paediatric Mattress (120cm x 60cm) - Complete Single Product	079063	5056279306058
Repose® Paediatric Mattress (150cm x 60cm) Complete Single Product	079064	5056279306072
Paediatric Mattress (120cm x 60cm) x10 & Pump x10	6181107	5056279306065
Repose® Paediatric Mattress (150cm x 60cm) x10 & Pump x10	6181108	5056279306089

Repose Babytherm (Bagged)	6400100	5056279301954
Repose Babytherm and Pump	6401100	5056279301961
Repose Babytherm and Pump (10 Pack)	6401101	5056279301985
Repose Paediatric Mattress (Bagged)	6800100	5056279302715
Repose Paediatric Mattress and Pump	6801100	5056279302791
Repose Baby Nest and Pump	6801101	5056279302814
Repose Paediatric Mattress and Pump ( 10 Pack)	6801102	5056279302838
Repose Baby Nest (Bagged)	6801103	5056279302845
Repose Baby Nest (without rim) + Pump	6801111	5056279302852
Repose Babytherm and Pump 10 singles	7401100	5056279303774
Repose Paediatric Mattress and Pump 10 singles	7801100	5056279303934
Repose Baby Nest and Pump 10 singles	7801101	5056279303941
Repose Baby Nest (without rim) + Pump 10 singles	7801111	5056279303958
<b>Note – This includes all variants and sizes of the above-stated products.</b>		

### Appendix 3.

#### Product List: Repose® and Enora® Covers.

Description	Product Codes (MPN)	UDI-DI
enora® Air Pump (Large) x1	8002271	5056279307659
enora® Air Pump (Small) x1	8002272	5056279307666
enora® Air Contur x1 w/Cover x1 & Air Sleeper x1 w/Cover x1 (Uplifting Blue) & Air Pump (Large) x1	8003020	5056279307178
enora® Air Contur x1 w/Cover x1 & Air Sleeper x1 w/Cover x1 (Glowing Green) & Air Pump (Large) x1	8003021	5056279307291
enora® Air Contur x1 w/Cover x1 & Air Sleeper x1 w/Cover x1 (Relieving Peach) & Air Pump (Large) x1	8003022	5056279307413
enora® Air Contur x1 w/Cover x1 & Air Sleeper x1 w/Cover x1 (Luminous Yellow) & Air Pump (Large) x1	8003023	5056279307536
enora® Air Sleeper x1 & Cover x1 (Uplifting Blue) & Air Pump (Large) x1	8004000	5056279307185
enora® Air Sleeper x1 & Cover x1 (Glowing Green) & Air Pump (Large) x1	8004001	5056279307307
enora® Air Sleeper x1 & Cover x1 (Relieving Peach) & Air Pump (Large) x1	8004002	5056279307420
enora® Air Sleeper x1 & Cover x1 (Luminous Yellow) & Air Pump (Large) x1	8004003	5056279307543
enora® Air Sleeper x1 & Cover x2 (Uplifting Blue) & Air Pump (Large) x1	8004010	5056279307192
enora® Air Sleeper x1 & Cover x2 (Glowing Green) & Air Pump (Large) x1	8004011	5056279307314
enora® Air Sleeper x1 & Cover x2 (Relieving Peach) & Air Pump (Large) x1	8004012	5056279307437
enora® Air Sleeper x1 & Cover x2 (Luminous Yellow) & Air Pump (Large) x1	8004013	5056279307550
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x1 w/Cover x1 (Uplifting Blue) & Air Pump (Large) x1	8004020	5056279307208
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x1 w/Cover x1 (Glowing Green) & Air Pump (Large) x1	8004021	5056279307321
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x1 w/Cover x1 (Relieving Peach) & Air Pump (Large) x1	8004022	5056279307444
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x1 w/Cover x1 (Luminous Yellow) & Air Pump (Large) x1	8004023	5056279307567
enora® Air Sleeper Cover x1 (Uplifting Blue)	8004030	5056279307048
enora® Air Sleeper Cover x1 (Glowing Green)	8004031	5056279307055
enora® Air Sleeper Cover x1 (Relieving Peach)	8004032	5056279307062
enora® Air Sleeper Cover x1 (Luminous Yellow)	8004033	5056279307079
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x2 w/Cover x2 (Uplifting Blue) & Air Pump (Large) x1	8004040	5056279307215
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x2 w/Cover x2 (Glowing Green) & Air Pump (Large) x1	8004041	5056279307338
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x2 w/Cover x2 (Relieving Peach) & Air Pump (Large) x1	8004042	5056279307451
enora® Air Sleeper x1 w/Cover x1 & Air Cushion x2 w/Cover x2 (Luminous Yellow) & Air Pump (Large) x1	8004043	5056279307574
enora® Air Sleeper Complete Single Product x1	8004050	5056279307628
enora® Air Sleeper Strap Extenders x2	8004070	5056279307642
enora® Air Sleeper x1 & Cover x1 (Uplifting Blue)	8004100	5056279308021
enora® Air Sleeper x1 & Cover x1 (Glowing Green)	8004101	5056279308038
enora® Air Sleeper x1 & Cover x1 (Relieving Peach)	8004102	5056279308045
enora® Air Sleeper x1 & Cover x1 (Relieving Peach)	8004103	5056279308052
enora® Air Sleeper x1 & Cover x1 (Uplifting Blue) - & Air Pump (Large) x1 - Amazon	8040000	5056279308182
enora® Air Sleeper x1 & Cover x1 (Glowing Green) & Air Pump (Large) x1 - Amazon	8040001	5056279308199
enora® Air Sleeper x1 & Cover x1 (Relieving Peach) & Air Pump (Large) x1 - Amazon	8040002	5056279308205
enora® Air Sleeper x1 & Cover x1 (Luminous Yellow) & Air Pump (Large) x1 - Amazon	8040003	5056279308212
<b>Note – This includes all variants and sizes of the above-stated products.</b>		

### Appendix 4.

#### 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
<b>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.</b>	

#### Appendix 5.

##### All Applicable Standards: Repose® Covers.

Standard 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 based. Ignition source: smouldering cigarette.	BS EN 597-1:2015
Furniture: Assessment of the ignitability of mattresses and upholstered bed based. Ignition source: match flame equivalent	BS EN 597-2:2015
<b>Note – The standards listed above are applicable for Repose product ranges ONLY stated within this document</b>	

#### Appendix 6.

##### All Applicable Standards: Enora® Covers.

Standard 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
<b>Note – The standards listed above are applicable for enora product ranges ONLY stated within this document</b>	






# EU Declaration - Repose Surface Solutions - I12

Final Audit Report

2025-07-24

Created:	2025-07-24
By:	Chris Dainton (cdainton@ftgroup.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAYDPIYkz9RrANFPITpvDr-FkUSbKWL_vs

## "EU Declaration - Repose Surface Solutions - I12" History

-  Document created by Chris Dainton (cdainton@ftgroup.uk)  
2025-07-24 - 3:23:30 PM GMT
-  Document emailed to Jimmy Yang (jyang@frontier-group.co.uk) for signature  
2025-07-24 - 3:24:17 PM GMT
-  Email viewed by Jimmy Yang (jyang@frontier-group.co.uk)  
2025-07-24 - 3:26:07 PM GMT
-  Document e-signed by Jimmy Yang (jyang@frontier-group.co.uk)  
Signature Date: 2025-07-24 - 3:26:23 PM GMT - Time Source: server
-  Agreement completed.  
2025-07-24 - 3:26:23 PM GMT