



# EU Declaration of Conformity



repose<sup>®</sup>      repose<sup>®</sup>  
ultra<sup>®</sup>core

## Pressure Relief Devices & Accessories

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



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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	Product Codes (MPN)	Description
5056279300902YT	6211110	Repose Blue Mattress Cover UK	5056279301589ZL	6181106	Repose Mattress (89 x 45cm) and Pump
50562793009192C	6211111	Repose Blue Mattress Cover EU	5056279302470YZ	6600100	Repose Trolley Mattress (Bagged)
505627930092629	6211112	Repose Long Mattress Cover EU	5056279302487ZJ	6601100	Repose Trolley Mattress and Pump
505627930098822	6980001	Repose Trolley Mattress Cover	5056279302494ZF	660110001	Repose TRAVERSA PER LETTIGHE E POMPA
5056377401008Y3	6990002	Repose Companion cover	5056279302500YH	6601101	Repose Trolley Mattress and Pump (10 Pack)
5056377401015XY	6990011	Repose Companion cover Thermal	5056279302517Z2	6680100	Repose Long Trolley Mattress (Bagged)
5056279301022XT	6990012	Repose Trolley Companion Cover	5056279302524YX	6681100	Repose Long Trolley Mattress and Pump
5056377401039YE	6991000	Repose 80 cm Companion Cover	5056279302531YU	6681101	Repose Long Trolley Mattress and Pump (10 Pack)
5056377401046YB	6991010	Repose Companion Cover - SAU	5056279302722Z5	6801000	Repose Pump (Long)
5056377401053Y8	6991011	Repose Companion Cover - SAU	5056279302739ZN	680100001	Repose POMPA (grande)
5056377401077YN	6991013	Repose Companion PB Cover - Loop handles	5056279302746ZK	6801001	Repose Pump (Long) REPROCESSED Carton of 10
5056279301084YH	9000001	Repose Ultracore Cover	5056279302753ZG	6801010	Repose Pump (Long) x10
5056279301091YE	9000002	Repose Ultracore EXPORT Cover	5056279302760ZD	680101001	Repose POMPA (grande) x10
5056279301152Y9	6011100	Repose Long Mattress and Pump	5056279302777ZW	6801011	Repose Pump (Short) x10
5056279301169YS	6011101	Repose Long Mattress and Pump (10 Pack)	5056279302784ZT	680101101	Repose POMPA (piccola) x10
5056279301176YP	6011102	Repose Long Mattress and Pump USA (6 Pack)	505627930286927	6802000	Repose Small Pump
5056279301275YS	6040101	Repose Long Trolley Mattress Repair Pack	505627930287624	680200001	Repose POMPA PICCOLA
5056279301312Y7	6100100	Repose Standard Mattress (Bagged)	5056279302883ZW	6802001	Repose Pump (Small) REPROCESSED Carton of 10
5056279301329YQ	6100101	Repose Standard Mattress (Bagged) x 10	5056279303316YV	6980002	Repose Repose Mattress Overlay Cover
5056279301336YM	6100105	Repose Short Mattress In Zip Lock Bag	5056377403323YU	6990003	Repose Companion Mattress and Pump
5056279301343YJ	6101000	Repose Mattress (60 x 80cm) (Bagged)	5056377403330YR	699000301	Repose SET DA TRASPORTO MATERASSO E POMPA
5056279301350YF	6101100	Repose Mattress and Pump	5056377403347ZA	6990004	Repose Companion and Mattress -2 Pack
5056279301367YY	610110001	Repose Traversa e pompa	5056377403354Z7	699000401	Repose SET DA TRASPORTO MATERASSO E POMPA - DUE PEZZ
5056279301374YV	6101101	Repose Mattress (120 x 65cm) and Pump	5056377403361Z4	6990005	Repose Red Companion and Mattress NO PUMP
5056279301381YS	6101102	Repose Mattress and Pump (10 Pack)	5056377403378ZM	6990010	Repose Red Companion and Mattress with pump
5056279301398ZB	610110201	Repose Traversa e pompa x 10	5056377403385ZJ	6990050	Repose Trolley Companion Set Single
5056279301404YD	6101110	Repose Mattress and Pump with PU Cover UK	5056377403392ZF	699005001	Repose Trolley Companion Singolo
5056279301411YA	6101111	Repose Mattress and Pump with PU Cover EU	5056377403408Z5	6990051	Repose Trolley Companion Set Pair
5056279301428YT	6111100	Repose Long Mattress and Pump (Bulk Pack 10)	5056279303415YY	6990100	Repose Inbo Mattress
5056279301435YQ	6111101	Repose Mattress and Pump (Bulk Pack)	5056279303422YV	6990110	Repose INBO mattress and Pump
5056279301466Z3	6121101	Repose Long Mattress	5056279303439ZE	6990111	Repose INBO Mattress and Pump (10 Pack)
5056279301473YY	6121102	Repose Mattress Cushion and Pump (10 Pack)	5056279303446ZB	6990112	Repose INBO mattress (70 cm) and Pump
5056279301480YV	6121103	Repose Long Mattress Cushion and Pump (10 Pack)	5056377403453ZA	6991001	Repose Companion
5056279301497ZE	6131100	Repose Double Mattress and small pump	5056279303460Z5	6991100	Repose Mattress (60 x 80cm) and Pump
5056279301503YG	613110001	Repose Traversa Matrimoniale e pompa	5056377403477ZQ	6992010	Repose Companion

5056279301510YD	6131101	Repose Double Mattress	5056377403484ZM	6992011	Repose Companion Trolley Mattress and pump
5056279301527YW	6180100	Repose Long Mattress (Bagged)	5056377403491ZJ	6992012	Repose Companion PB
5056279301534YT	6180102	Repose Mattress (70 x 45 cm) and Pump	5056279303507Z6	7101101	Repose Mattress (120 x 65cm) and Pump 10 singles
5056279301541YQ	6181100	Repose Mattress (38 x 72cm) and Pump	5056279303521YY	7601100	Repose Trolley Mattress and Pump 10 singles
5056279301558Z9	6181103	Repose Mattress (74 x 54cm) and Pump	5056279303538ZH	7680100	Repose Long Trolley Mattress (Bagged) 10 singles
5056279301565Z6	6181104	Repose Mattress (140 x 70cm) and Pump	5056279303545ZE	7681100	Repose Long Trolley Mattress and Pump 10 singles
5056279301572Z3	6181105	Repose Mattress (75 x 43cm) and Pump	5056279303552ZB	7991100	Repose Mattress (60 x 80cm) and Pump 10 singles
5056279303583ZN	9100012	Repose Ultracore Plus	5056279303569ZU	9000020	Repose Ultracore Inner / Overlay
5056279303590ZK	9100013	Repose Ultracore EXPORT	5056279303576ZR	9100011	Repose Ultracore
5056279303606Z9	9100014	Repose Ultracore Plus EXPORT	5056279305037Z4	6100112	Mattress Overlay with Extra Long TPU Straps
5056279303613Z6	7011100	Repose Long Mattress and Pump 10 singles	5056279305044YZ	6100113	Mattress Overlay with Extra Long TPU Straps
5056279303644ZH	7101100	Repose Mattress and Pump 10 singles	5056279305051YW	6100114	Mattress Overlay with Extra Long TPU Straps
5056279303651ZE	710110001	Repose Traversa e pompa 10 singole	5056279305068ZF	6100115	Mattress Overlay with TPU Straps
5056279303668Z2	7101101	Repose Mattress (120 x 65cm) and Pump 10 singles	5056279305075ZC	6100116	Mattress Overlay with TPU Straps
5056279303675ZU	7121100	Repose Mattress Cushion and Pump 10 singles	5056279305082Z9	6100117	Mattress Overlay with TPU Straps
5056279303682ZR	7121101	Repose Long Mattress Cushion and Pump 10 singles	5056279305099ZS	6100118	Mattress Overlay with TPU Straps
5056279303699ZD	7180102	Repose Mattress (70 x 45cm) and Pump 10 singles	5056279305105YU	6100119	Mattress Overlay with TPU Straps
5056279303705ZC	7181100	Repose Mattress (38 x 72cm) and Pump 10 singles	5056279305129ZA	6141001	Prone Mattress Overlay
5056279303712Z9	7181103	Repose Mattress (74 x 54cm) and Pump 10 singles	5056279305136Z7	6141010	Prone Mattress Overlay
5056279303729ZS	7181104	Repose Mattress (140 x 70cm) and Pump 10 singles	5056279305143Z4	6141100	Prone Mattress Overlay
5056279303736ZP	7181105	Repose Mattress (75 x 43cm) and Pump 10 singles	5056279305150YZ	7141100	Prone Mattress Overlay
5056279303866Z8	7601100	Repose Trolley Mattress and Pump 10 singles	5056279305167ZJ	6141110	Prone Mattress Overlay
5056279303873Z5	7680100	Repose Long Trolley Mattress (Bagged) 10 singles	5056279305174ZF	6141101	Prone Mattress Overlay
5056279303880Z2	7681100	Repose Long Trolley Mattress and Pump 10 singles	5056279305303Z2	6170101	Prone Kit
5056279303927Z3	7801000	Repose Pump (Long) 10 singles	5056279305310YX	6170110	Prone Kit
5056279303965ZB	7802000	Repose Small Pump 10 singles	5056279305327ZG	6170102	Prone Kit
5056279304023YJ	7990110	Repose INBO mattress and Pump 10 singles	5056279305334ZD	7170102	Prone Kit
5056279304030YF	7990112	Repose INBO mattress (70 cm) and Pump 10 singles	5056279305341ZA	6170112	Prone Kit
5056279304047YY	7991100	Repose Mattress (60 x 80cm) and Pump 10 singles	5056279305358ZT	6170111	Prone Kit
5056279304344Z9	6101110	Mattress Overlay Set - UK	5056279305372ZM	6803000	Ultracore Pump
5056279304351Z6	6101111	Mattress Overlay Set - EU	5056279305389Z9	7803000	Ultracore Pump
5056279304757Z9	6050111	Mattress Overlay Refresh Cover	5056279305396Z6	6803010	Ultracore Pump
5056279304832ZT	6131101	Repose Double Mattress Overlay (No Pump)	5056279305501Z8	6011103	Repose Mattress Overlay Long and Cover (No Pump)
5056279304849ZF	6270001	Repose Mattress Overlay Lite for Ultracore - Single	5056279305013YN	6100110	Mattress Overlay with Extra Long TPU Straps
5056279304856ZC	6000003	Mattress Overlay Extension Strap - TPU	5056279305020YK	6100111	Mattress Overlay with Extra Long TPU Straps
5056279304924Z4	6050113	Mattress Overlay Refresh Cover with Extra Long TPU Strap	5056279304931ZW	6050114	Mattress Overlay Refresh Cover with Extra Long TPU Strap
5056279304917Z7	9200010	Ultracore Repose® Lite Inside	5056279305365ZQ	9200001	Ultracore Repose® Lite Inside - Cover

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\_Surface\_Solutions\_I1

Final Audit Report

2021-05-21

Created:	2021-05-21
By:	Simon Bosley (sbosley@frontier-group.co.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAADYziDy6w68cOI_jw9gJ60tvmGLTJj3LX

## "EU Declaration - Repose\_Surface\_Solutions\_I1" History

-  Document created by Simon Bosley (sbosley@frontier-group.co.uk)  
2021-05-21 - 2:39:09 PM GMT- IP address: 46.231.70.26
-  Document emailed to Simon Jackson (sjackson@frontier-group.co.uk) for signature  
2021-05-21 - 2:39:25 PM GMT
-  Email viewed by Simon Jackson (sjackson@frontier-group.co.uk)  
2021-05-21 - 2:42:22 PM GMT- IP address: 104.47.20.254
-  Document e-signed by Simon Jackson (sjackson@frontier-group.co.uk)  
Signature Date: 2021-05-21 - 2:42:50 PM GMT - Time Source: server- IP address: 86.163.1.226
-  Agreement completed.  
2021-05-21 - 2:42:50 PM GMT