# EU Declaration of Conformity

## Pressure Relief Devices & Accessories

Repose Basic-UDI = 50562793ReposeGN
(See Appendix 1 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

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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 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 2 & 3** 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 Single Long Footprotector (Bagged) | 6020000 | 5056279301183 |
| Repose Pair Long Footprotector (Bagged) | 6020001 | 5056279301190 |
| Repose Single Footprotector and Pump (10 Pack) | 6020002 | 5056279301206 |
| Repose Footprotectors (Pair) and Pump USA | 6020003 | 5056279301213 |
| Repose Single Long Footprotector and Pump | 6021000 | 5056279301220 |
| Repose Single Long Footprotector and Pump (10 Pack) | 6021001 | 5056279301237 |
| Repose Long Footprotectors (Pair) and Pump | 6021100 | 5056279301244 |
| Repose Long Footprotectors (Pair) and Pump (Pack of 10) | 6021102 | 5056279301251 |
| Repose® Lite Foot Protector (Single) | 6260001 | 5056279306027 |
| Repose Single Footprotector (Bagged) | 6500020 | 5056279301992 |
| Repose Footprotectors (Pair) (Bagged) | 6500100 | 5056279302005 |
| Repose Footprotectors (Pair) (Bagged) x 10 - no pump | 6500101 | 5056279302012 |
| Repose Footprotector (Pair) (Bulk Pack 10) | 6500200 | 5056279302029 |
| Repose Long Footprotectors (Pair) (Bulk Pack 10) | 6500201 | 5056279302036 |
| Repose Hospidex Footprotector (Pair) (Bulk Pack) | 6500202 | 5056279302043 |
| 4 Layer Standard Footprotector with Magnafix (Pair) (Bulk Pack 10) | 6500300 | 5056279304269 |
| 4 Layer Large Footprotector with Magnafix (Pair) (Bulk Pack 10) | 6500301 | 5056279304276 |
| Repose Single Footprotector and Pump | 6501020 | 5056279302050 |
| Repose Single Footprotector and Pump Hospidex | 6501021 | 5056279302067 |
| Repose Footprotectors (Pair) and Pump | 6501100 | 5056279302074 |
| Repose Footprotectors (Pair) and Pump (10 Pack) | 6501101 | 5056279302098 |
| Repose Hospidex Footprotectors (Pair) and Pump - FRANCE | 6501102 | 5056279302104 |
| Repose Hospidex Footprotector (10 Pr) and Pump - FRANCE | 6501103 | 5056279302111 |
| Repose Hospidex Footprotector (20 Pr) and Pump - FRANCE | 6501104 | 5056279302128 |
| Repose Hospidex Footprotector Lg(10S) and Pump - FRANCE | 6501105 | 5056279302135 |
| Repose Hospidex Footprotector Lg (Pr) and Pump x 1 - FRANCE | 6501106 | 5056279302142 |
| Repose Footprotector PLUS (Pair) and pump | 6511100 | 5056279302159 |
| Repose Footprotector PLUS (Single) and pump | 6511101 | 5056279302173 |
| Repose Footprotector PLUS (Single) In Zip Bag + Leaflet | 6511102 | 5056279302197 |
| Repose Footprotector PLUS (Pair) In Zip Bag + Leaflet | 6511103 | 5056279302203 |
| Repose Single Footprotector PLUS and Pump | 6511104 | 5056279302210 |
| Repose Footprotector PLUS (Pair) x10 no pump | 6511105 | 5056279302234 |
| Repose Footprotectors PLUS (Pair) and Pump (10 Pack) | 6511106 | 5056279302241 |
| Repose Footprotector Plus (Pair) (Bulk Pack 10) | 6511110 | 5056279302258 |
| Repose Small Footprotector (Bulk Pack 10) with pump | 6520100 | 5056279302296 |
| Repose Small Footprotectors (Pair) and Pump | 6521100 | 5056279302302 |
| Repose Small Footprotectors (Pair) and Pump (10 Pack) | 6521101 | 5056279302319 |
| Repose Small Footprotectors (Single) and Pump | 6521102 | 5056279302326 |
| Repose Small Footprotectors (Pair) and Pump - HOSPIDEX | 6521103 | 5056279302333 |
| Repose Extra Small Footprotector (Bulk Pack 10) with pump | 6530100 | 5056279302340 |
| Repose Extra Small Footprotectors (Pair) and Pump | 6531100 | 5056279302357 |
| Repose Extra Small Footprotectors (Pair) and Pump (10 Pack) | 6531101 | 5056279302364 |
| Repose Extra Small Footprotectors (Single) and Pump | 6531102 | 5056279302371 |
| Repose Extra Small Footprotectors (Pair) and Pump - HOSPIDEX | 6531103 | 5056279302388 |
| Repose Small Footprotector Plus (Bulk Pack 10) with pump | 6540100 | 5056279302395 |
| Repose Small Footprotectors Plus (Pair) and Pump | 6541100 | 5056279302401 |
| Repose Small Footprotectors Plus (Pair) and Pump (10 Pack) | 6541101 | 5056279302418 |
| Repose Small Footprotectors Plus (Single) and Pump | 6541103 | 5056279302425 |
| Repose Foot Protector with Magnafix - Standard Size - 4 Layers (Pair) with pump | 6542000 | 5056279304245 |
| Repose Foot Protector with Magnafix - Large Size - 4 Layers (Pair) with pump | 6542001 | 5056279304252 |
| Repose Extra Small Footprotector Plus (Bulk Pack 10) with pump | 6550100 | 5056279302432 |
| Repose Extra Small Footprotectors Plus (Pair) and Pump | 6551100 | 5056279302449 |
| Repose Extra Small Footprotectors Plus (Pair) and Pump (10 Pack) | 6551101 | 5056279302456 |
| Repose Extra Small Footprotectors Plus (Single) and Pump | 6551103 | 5056279302463 |
| Repose Wedge (Bagged) | 6700100 | 5056279302548 |
| Repose Wedge (Bulk Pack) | 6700101 | 5056279302555 |
| Repose Wedge (with Strap) (Bulk Pack 10) | 6700102 | 5056279302562 |
| Repose Wedge (with Strap) (Bagged) | 6710100 | 5056279302579 |
| Repose Wedge (with Strap) (Bagged) x 10 | 6710101 | 5056279302586 |
| Repose Wedge (with Strap) and Pump | 6711100 | 5056279302593 |
| Repose Wedge (with Strap) and Pump (1 0 Pack) | 6711101 | 5056279302616 |

| | | |
|---|---|---|
| 1x Repose Wedge (without strap) with PU Cover | 6711103 | 5056279306843 |
| Repose Wedge (with PU Strap) Bagged | 6711110 | 5056279302623 |
| Repose Wedge (with PU Strap) with pump | 6711111 | 5056279302630 |
| Repose Wedge (with PU Strap) x10 with small pump (Bulk Pack) | 6711112 | 5056279302647 |
| Repose Wedge (with PU Strap)x10 no Pump | 6711113 | 5056279302654 |
| Repose Wedge (With PU Strap) with Pump (10 Pack) | 6711114 | 5056279302661 |
| Wedge with Extra Long TPU Strap - 1 x STD Wedge | 6711115 | 5056279304870 |
| Wedge with Extra Long TPU Strap - 1 x STD Wedge and 1 x SML Pump | 6711116 | 5056279304887 |
| Wedge with Extra Long TPU Strap - 10 x STD Wedge and 1 x SML Pump | 6711117 | 5056279304894 |
| Wedge with Extra Long TPU Strap - 10 x STD Wedge | 6711118 | 5056279304900 |
| Repose Flex - Extra Small 1 Flex and pump | 6750000 | 5056279302678 |
| Repose Flex - Small 1 Flex and pump | 6750001 | 5056279302685 |
| Repose Flex - Standard 1 Flex and pump | 6750002 | 5056279302692 |
| Repose Flex - Extra Small - 10 Products and 10 Pumps | 6750010 | 5056279304641 |
| Repose Flex - Small - 10 Products and 10 Pumps | 6750011 | 5056279304689 |
| Repose Flex - Standard - 10 Products and 10 Pumps | 6750012 | 5056279304726 |
| Repose Flex - Extra Small - 10 Products and 1 Pump | 6750110 | 5056279304658 |
| Repose Flex - Small - 10 Products and 1 Pump | 6750111 | 5056279304696 |
| Repose Flex - Standard - 10 Products and 1 Pump | 6750112 | 5056279304733 |
| Repose Flex - Extra Small - 10 Products (No Pump) | 6750210 | 5056279304665 |
| Repose Flex - Small - 10 Products (No Pump) | 6750211 | 5056279304702 |
| Repose Flex - Standard - 10 Products (No Pump) | 6750212 | 5056279304740 |
| Repose® Wedge Cover UK | 6760000 | 5056279306140 |
| Repose® Flex Cover UK | 6760002 | 5056279306164 |
| Repose Wedge (without Strap) Bagged | 6760009 | 5056279306836 |
| Repose Wedge without strap, 1x Small Pump, 1x Repose Wedge PU Cover | 6760011 | 5056279306812 |
| Repose® Flex without strap (Bagged) standard x1 & Cover x1 | 6760012 | 5056279306898 |
| Repose® Flex without strap standard x1 & Cover x1 & Pump x1 | 6760013 | 5056279306881 |
| Repose Flex (without strap) with PU Cover | 6760014 | 5056279306805 |
| Wedge - Extra Large x 1 (Bagged) | 6821001 | 5056279305181 |
| Wedge - Large x 10 & Pump x 1 (Bulk Pack) | 6821011 | 5056279305235 |
| Wedge - Extra Large x 1 & Pump x 1 | 6821100 | 5056279302890 |
| Wedge - Extra Large x 10 & Pump x 10 (Bulk Pack) | 6821110 | 5056279305228 |
| Repose Wedge (50cm) (Bagged) | 6910100 | 5056279303224 |
| Repose Wedge (50cm with Strap) | 6920100 | 5056279303231 |
| Wedge Without Strap - Extra Large x 1 (Bagged) | 6921001 | 5056279305242 |
| Wedge Without Strap - Large | 6921010 | 5056279305259 |
| Extra Large Wedge Without Strap x 10 and 10 pumps (Bulk Pack) | 6921011 | 5056279305280 |
| Repose Wedge (50cm) and Pump | 6921100 | 5056279303248 |
| Wedge Without Strap - Extra Large x 10 & Pump x 10 (Bulk Pack) | 6921101 | 5056279303255 |
| Wedge Without Strap - Extra Large x 10 & Pump x 1 (Bulk Pack) | 6921110 | 5056279305297 |
| Repose® Wedge With TPU Strap x1 | 6922001 | 5056279305747 |
| Repose® Wedge With TPU Strap Large x1 & Pump x1 | 6922011 | 5056279305754 |
| Repose® Wedge With TPU Strap Large x10 & Pump x10 | 6922101 | 5056279305761 |
| Repose Sole Protector x 1 in zip lock bag | 6930000 | 5056279303262 |
| Repose Sole Protector x 1 with Small Pump | 6930001 | 5056279303279 |
| Repose Sole Protector bagged x 10 no Pump | 6930009 | 5056279303293 |
| Repose Sole Protector x 10 with Small Pump | 6930010 | 5056279303309 |
| Repose 1 Long Footprotector and pump 10 singles | 7021000 | 5056279303620 |
| Repose Long Footprotectors (Pair) and Pump - 10 singles | 7021100 | 5056279303637 |
| Repose Single Footprotector and Pump 10 singles | 7501020 | 5056279303781 |
| Repose Hospidex - Footprotectors and pumps - 10 singles | 7501021 | 5056279303798 |
| Repose Footprotectors (Pair) and Pump 10 singles | 7501100 | 5056279303804 |
| Repose Hospidex Footprotector (Pairs) and Pumps - 10 singles France | 7501102 | 5056279303811 |
| Repose Hospidex Footprotector Lg (Pr) and Pump - 10 singles | 7501106 | 5056279303514 |
| Repose Footprotector PLUS (Pair) and pump - 10 singles | 7511100 | 5056279303835 |
| Repose Footprotector plus ( Singles) and pump - 10 singles | 7511101 | 5056279303842 |
| Small Foot Protector (pair) and pump - 10 singles | 7521100 | 5056279304627 |
| 4 Layer Footprotector with Magnafix (Pair) - Standard Size (Bulk Pack 10) | 7542000 | 5056279304306 |
| 4 Layer Footprotector with Magnafix (Pair) - Large Size (Bulk Pack 10) | 7542001 | 5056279304313 |
| Repose Wedge and Pump 10 singles | 7701100 | 5056279303897 |
| Repose Wedge (with Strap) and Pump 10 singles | 7711100 | 5056279303903 |
| Repose Flex - Extra Small 10 Products and 10 Pumps (individually boxed) | 7750000 | 5056279304795 |
| Repose Flex - Small 10 Products and 10 Pumps (Individually Boxed) | 7750001 | 5056279304801 |
| Repose Flex - Standard (1 Flex and pump) 10 Singles | 7750002 | 5056279304610 |
| Extra Large Wedge x 10 & Pump x 10 (10 Singles) | 7821100 | 5056279303972 |

| | | |
|---|---|---|
| Repose Wedge (50cm) and Pump 10 singles | 7921100 | 5056279303989 |
| Repose Wedge (50cm 5 Tubes) and Pump 10 singles | 7921101 | 5056279303996 |
| Repose Sole Protector and Pump 10 singles | 7930001 | 5056279304009 |
| Repose Protezione piede x2 e pompa | 650110001 | 5056279302081 |
| Repose Protezione piede PLUS x2 e pompa | 651110001 | 5056279302166 |
| Repose Protezione piede PLUS singolo e pompa | 651110101 | 5056279302180 |
| Repose Protezione piede PLUS singolo x 10 e pompa | 651110401 | 5056279302227 |
| Repose Protezione piede PLUS coppia x 10 e pompa | 651111001 | 5056279302265 |
| Repose Protezione piede PLUS coppia e pompa x 10 | 651111101 | 5056279302272 |
| Repose Protezione piede PLUS singolo e pompa x 10 | 651111401 | 5056279302289 |
| Repose Flex - extra piccolo e pompa | 675000001 | 5056279304153 |
| Repose Flex - piccolo e pompa | 675000101 | 5056279304160 |
| Repose Flex - standard e pompa | 675000201 | 5056279304177 |
| Repose Sole Protector x 1 e pumpa | 693000101 | 5056279303286 |
| Repose Protezione piede PLUS singolo e pompa - 10 singole | 751110101 | 5056279303859 |
| TRAVERSA PER LETTIGHE E POMPA | 760110001 | 5056279304184 |
| Repose Cuscino di sostegno 10 singloe | 771110001 | 5056279303910 |
| Repose Flex - extra piccolo e pompa | 775000001 | 5056279304191 |
| Repose Flex - piccolo e pompa | 775000101 | 5056279304207 |
| Repose Flex - standard e pompa | 775000201 | 5056279304214 |
| Repose Sole Protector e pompa 10 singloe | 793000101 | 5056279304016 |

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

**Appendix 2.**

**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 |

**Appendix 3.**

**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**

# EU Declaration - Repose Footcare Solutions I10

Final Audit Report 2025-07-25

| | |
|---|---|
| Created: | 2025-07-25 |
| By: | Chris Dainton (cdainton@ftgroup.uk) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAYm8v8ZaMyneo7r5d7yaJVoJQ3sO1R8j1 |

## "EU Declaration - Repose Footcare Solutions I10" History

Document created by Chris Dainton (cdainton@ftgroup.uk)
2025-07-25 - 3:41:50 PM GMT

Document emailed to Jimmy Yang (jyang@frontier-group.co.uk) for signature
2025-07-25 - 3:42:51 PM GMT

Email viewed by Jimmy Yang (jyang@frontier-group.co.uk)
2025-07-25 - 7:36:33 PM GMT

Document e-signed by Jimmy Yang (jyang@frontier-group.co.uk)
Signature Date: 2025-07-25 - 7:37:02 PM GMT - Time Source: server

Agreement completed.
2025-07-25 - 7:37:02 PM GMT