PRESSALIT®

United Kingdom Conformity Assessment

United Kingdom RP:
Pressalit Ltd.
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This product is produced in compliance with all relevant requirements of:
- Regulation (EU) 2017/745 on medical devices (Risk class I, rule 1)
- Council Directive 2006/42/EC on machinery
- Council Directive 2011/65/EC on RoHS

For the UK:
- Medical Device Regulation (MDR) 2002 on medical devices
- Supply of Machinery (Safety) Regulations 2008
- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

Medical devices - Application of risk management and quality management in design and production	ISO 14971:2019 ISO 13485:2016

The products are manufactured in accordance with the following standards:	IEC 60601-1:2005 ISO 17966:2016

Ry, 27. maj 2026

Mette Elstrøm Kristoffersen, QA/RA Specialist, Pressalit A/S
Responsible

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SCT 2100

REF **R8581418000D**

EAN (GTIN):

Nomenclature (EMDN): Y093312

Name

EN

Intended purpose

EN This product is intended for showering or changing a person who is unable to stand or sit. The person is lying horizontally on the table.
Expected service life is 10 years for institutional use, provided that maintenance is carried out as described in the user manual.