

Declaration of Conformity

Lejrelet



Direct Healthcare Group Ltd., Withey Court, Western Industrial Estate, Caerphilly, United Kingdom, CF83 1BF hereby declare that the products identified below conform to the requirements of the Medical Device Regulations 2017/745.

Product Details	
Product Name	See schedule
Legal Manufacturer	Direct Healthcare Group Limited, Withey Court, Western Industrial Estate, Caerphilly, United Kingdom, CF83 1BF
Intended Use	The Lejrelet product range offers support, positioning and pressure relief
Device classification	Class I under rule 1 of Annex VIII
Route to classification	Self-certification following compliance with the requirements of Annex II and Annex III of MDR 2017/745.

The following standards have been used to fulfil the Medical Device Regulations and Requirements:

Standard/Document Name	Description
EN ISO 13485: 2016	Medical devices — Quality management system
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2020	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical device
BS EN ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
BS EN ISO 10993-10:2013	Biological evaluation of medical devices. Tests for irritation and skin sensitization

Representative/Sponsor	Address
EU Authorised Representative	Direct Healthcare Group Sverige AB, Torshamnsgatan 35, SE-164 40 Kista, Sweden
Australian sponsor	Direct Healthcare Group PTY Ltd., 67 Howe Street, Osborne Park, Western Australia 6017

Signature: 

Date: 8 June 2022

Jo Campbell, QARA Director, Direct Healthcare Group Limited, Caerphilly, United Kingdom

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Schedule – Product Listing

Description	Product Code	Basic UDI
Lejrelet Tube 125	5000000	05060572010192
Lejrelet Tube 250	5000001	05060572010307
Lejrelet Wedge	5000002	05060572010314
Lejrelet Pad High	5000003	05060572010321
Lejrelet Pad Low	5000004	05060572010338
Lejrelet Oval	5000009	05060572010345