Declaration of Conformity

Patient Support System Cushion (DOC-TF106)

Direct Healthcare Group Ltd, hereby declare that the products identified below confirm to the requirements of the Medical Device Regulation 2017/475.

This Declaration of Conformity is issued under the sole responsibility of Direct Healthcare Group Ltd.

Declaration Ref:	DOC-TF106
General Product Name:	Patient Support System Cushion
Date of Declaration of Conformity:	27 February 2026
Manufacturer:	Direct Healthcare Group Ltd Withey Court, Western Industrial Estate, Caerphilly, CF83 1BF, United Kingdom
Manufacturer SRN:	UK-MF-000037574
Product Code:	As per Appendix I – Product Listing/Schedule
Intended Use:	Intended for both prevention and treatment of pressure ulcers and are intended to be used in conjunction with an appropriately sized chair / wheelchair, as part of an overall pressure ulcer prevention program of care
EMDN:	V08030102 – Non-Active Anti-Decubitus Medical Cushions
Basic-UDI-DI:	0506057201PSSC8V
Measuring function:	No
Sterile:	No
Standards referenced or applied:	As per Appendix II – Applicable Standards
Conformity assessment Procedure:	Regulation (EU) 2017/745 on medical devices (MDR) Annex II and III
Regulation Classification:	Class I Rule 1 (Annex VIII)
Notified Body:	N/A
EC Certificate Ref:	N/A
EU Authorised Representative:	Direct Healthcare Group Sverige AB (DHG AB) Torshamnsgatan 35, SE-164 40 Kista, Sweden SE-AR-000014155
Australian Sponsor	Direct Healthcare Group PTY LTd, 67 Howe Street, Osborne Park, Western Australia 6017

Declaration of Conformity

Patient Support System Cushion (DOC-TF106)

Moving Health Forward

Sign for and on behalf of Direct Healthcare Group by:

R.W.Macdonald

R W Macdonald — Caerphilly, United Kingdom

Group Regulatory Affairs Director — 26th February 2026

Version History

Revision	Compiled by	Date	Description
4.0	R.W. Macdonald	27/02/2026	Updated format, corrected declaration reference and removal of 'Note: powered version'
3.0	K. Chima	03/09/2025	Addition of Integrity Cushion Range
2.0	R.W. Macdonald	21/01/2025	Updated format
1.0	J Campbell	02/02/2022	Initial release for MDR

Appendix I – Product Listing/Schedule

Catalogue Ref	Device Name
POS0110001	Dyna-Tek Heel Boots
POS0210001	Dyna-Tek Heel Pads
POS0310001	Dyna-Tek Pad Wedge
CUS05	Dyna-Tek Profile Cushion
CUS01	Dyna-Tek Pad Cushion
CUS0110007	Dyna-Tek Pad Low Profile Cushion
CUS02	Dyna-Tek Superior Pad Cushion
CUS04	Dyna-Flex Cushion
CUS0410007	Dyna-Flex Low Profile Cushion
CUS0410000	Dyna-Flex Bari
CUS0210000	Dyna-Pad Superior Bari
CUS03	Dyna-Tek Owl Cushion
CUS07	Dyna-Tek Gel Cushion
CUS06	Dyna-Tek Posture Visco Cushion
CUS08	Dyna-Tek Intelligent Air Cushion
CUS0810007	Dyna- Tek Low Profile Intelligent Air Cushion
CUS09	Transflo Cushion - Up to 21"
CUS0920000	Transflo Cushion Leisure - Up to 21"
CUS0930000	Transflo Cushion Heavy Duty - Up to 21"
CUS0940000	Transflo Cushion Bari - Up to 36"
CUS0950000	Transflo Cushion Wedge - Up to 21"
CUS0960000	Transflo Cushion Ellipse - Up to 21"
CUS0970000	Transflo Cushion Contoured - Up to 21"
CUS0980000	Transflo Cushion Contoured Heavy Duty - Up to 21"
CUS0910099	Transflo Cushion Special
5000000	Lejrelet Tube 125
5000001	Lejrelet Tube 250
5000002	Lejrelet Wedge
5000003	Lejrelet Pad High
5000004	Lejrelet Pad Low
5000009	Lejrelet Oval

Catalogue Ref	Device Name
INTE	Integrity Static Cushion
INTH	Integrity Static Cushion – High Risk
INTL	Integrity Static Cushion – Low Risk
INTM	Integrity Static Cushion – Medium Risk
INTV	The Integrity Static Cushion – Very High Risk
INTSTATAIR	Integrity Static Air Cushion

Appendix II – Applicable Standards

The current Declaration of Conformity is also in conformity with the following European Standards and Common Specifications (CS):

Reference	Version/Year	Title
BS EN ISO 13485	2016+A11:2021	Medical devices. Quality management systems. Requirements for regulatory purposes
BS EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices
BS EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1. Evaluation and testing within a risk management process
BS EN ISO 15223-1	2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
BS EN ISO 20417	2021	Medical devices. Information to be supplied by the manufacturer
BS EN 62366-1	2015+A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices
BS 7176	2007+A1:2011	Specification for resistance to ignition of upholstered furniture for non-domestic seating by testing composites
BS 5852	2006	Methods of test for assessment of the ignitability of upholstered seating by smouldering and flaming ignition sources
BS EN 21856	2022	Assistive products - General requirements and test methods (ISO 21856:2022)

Appendix III – Additional Information

No Additional information is required.