Declaration of Conformity

Static Foam Support Products (DOC-101)

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-101
General Product Name:	Static Foam Support Products
Date of Declaration of Conformity:	February 2025
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 to be used with appropriately sized bed frames to offer pressure redistribution for both prevention and treatment of pressure ulcers as part of an overall pressure ulcer prevention program of care.
EMDN:	V080702 – Non-Active Anti-Decubitus Medical Mattresses
Basic-UDI-DI:	506057201SFSP8B
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

Sign for and on behalf of Direct Healthcare Group by:

R.W. Macdonald

R W Macdonald	Caerphilly, United Kingdom
Group Regulatory Affairs Director	11th Feb 2025

Version History

Revision	Compiled by	Date	Description
3.0	R.W. Macdonald	11/02/2025	Updated format
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
MAT01	Dyna-Form Mercury
MAT02	Dyna-Form Jupiter
MAT03	Dyna-Form Saturn
MAT04	Dyna-Pad Double Overlay
MAT0410001	Dyna-Pad Overlay
MAT0410080	Dyna-Form Trolley Mattress
MAT05	Dyna-Form Static Air HZ
MAT06	Dyna-Form Mercury Fire Evac
MAT07	Dyna-Form Mercury Safety 7
MAT08	Dyna-Form Static Air
MAT09	Dyna-Form Maximus
MAT21	Dyna-Form Overlay Superior
MAT24	Dyna-Form Community

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	Medical Devices – Part 1: Application of usability engineering to medical devices
BS EN 21856	2022	Assistive products - General requirements and test methods (ISO 21856:2022)
BS 7177	2008+A1:2011	Specification for resistance to ignitions of mattresses, mattress pads, divans and bed bases

Appendix III – Additional Information

No Additional information is required.