



Moving Health Forward

Declaration of Conformity

Direct Healthcare Group Ltd., Withey Court, Western Industrial Estate, Caerphilly, United Kingdom, CF83 1BF hereby declare that the products identified below conform to the essential requirements of the Medical Device Directive 93/42/EEC, this conformance having been demonstrated in accordance with the full quality assurance conformity assessment procedure defined by Annex II of that directive (excluding section 4) for class II(a) devices under Annex IX rule 9.

Product Name	Product Code	UDI-DI
Dyna-Form Mercury Advance Mattress System	MAS12	5060407340029
Dyna-Form Mercury Advance Mattress	MAT12	5060572019928
Dyna-Form Mercury Advance Trolley Mattress System	MAS35	5060572015333
Dyna-Form Mercury Advance Trolley Mattress	MAT35	5060572015340
Dyna-Form Mercury Advance Trolley Mattress	MAT1260001	5060572015340
Dyna-Form Mercury Advance SMARTcare Mattress System	MAS16	5060572014930
Dyna-Form Mercury Advance SMARTcare Mattress	MAT16	5060572014954
Dyna-Form Mercury Advance Cushion	CUS12	5060572014947
Dyna-Form Mercury Advance SMARTcare Control Unit	PUM12	5060407340005
Dyna-Form Mercury Advance Bari Mattress System	MAS15	5060572019942
Dyna-Form Mercury Advance Bari Mattress	MAT15	5060572019959
Dyna-Form Mercury Advance Bari Width Adjustable Mattress System	MAS31	5056839700401
Dyna-Form Mercury Advance Bari Width Adjustable Mattress	MAT31	5060407347196
Dyna-Form Mercury Advance SMARTcare Bari Control Unit	PUM15	5060407340081
Dyna-Form SMARTresponse Mattress System	MAS32	5060572012585
Dyna-Form SMARTresponse Mattress	MAT32	5060572015289
Dyna-Form SMARTresponse Control Unit	PUM32	5060572015272
Dyna-Form Mercury Advance Community Mattress System	MAS27	5060572015319
Dyna-Form Mercury Advance Community Mattress	MAT27	5060572015074
Community Control Unit	PUM17	5060572015265

The conformance of the products detailed has been evaluated by the Notified Body PCBC, NB 1434, who granted the CE Mark under the CE Marking certificate MDD-1434-302/2020. Direct Healthcare Group is registered with the Competent Authority (MHRA), reference number 6820. These products are under the sole responsibility of the manufacturer.

The following standards have been used to ensure compliance:

BS EN ISO 13485:2016+A11:2021	BS EN 60601-1-11:2015+A1:2021
BS EN ISO 14971:2019+A11:2021	BS EN 60601-1-2: 2015+A1:2021
BS EN ISO 10993-1:2020	BS EN 60601-1:2006+A2:2021
BS EN ISO 10993-10:2023	BS EN 60601-1-6:2010+A2:2021
BS EN ISO 10993-23:2021	BS EN 62366-1:2015+A1:2020
BS EN ISO 15223-1:2021	BS EN 597-1: 2015
BS EN ISO 20417:2021	BS EN 597-2: 2015
BS EN 62304:2006+A1:2015	BS 7177: 2008+A1:2011

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: *Kiran Chima*

Date: 26 FEB 2026

Kiran Chima, Senior Regulatory Affairs Associate