DHG

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
Dyna-Form Mercury Advance	MAT12
Dyna-Form Mercury Advance Bari Width Adjustable	MAT31
Mercury Advance SMARTcare	MAT16
Dyna-Form Air Suresse	MAT1110001
Dyna-Form Mercury Advance Community	MAT27

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, valid from 11 August 2020 to 16 June 2023. Direct Healthcare Group is registered with the Competent Authority (MHRA), reference number 6820.

The following harmonized standards have been used to ensure compliance:	
BS EN ISO 14971:2019	BS EN 60601-1-6:2010+A1:2015
BS EN ISO 13485:2016	BS EN 60601-1-11:2015
BS EN 60601-1:2006/A1:2013	BS EN 10993-5:2009
BS EN 60601-1-2:2015	BS EN 10993-10:2013

The following additional standards have been used to ensure compliance:	
BS 7177:2008+A1:2011	BS EN 597-2:1994
BS EN 597-1:1995	BS EN ISO 15223-1:2012

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:

Jo Campbell, QARA Director

Date: 2 February 2022