Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

MANUFACTURER:	Ortho-Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom
CONTRACT MANUFACTURER:	Millipore UK Ltd. Fleming Rd. Kirkton Campus Livingston EH54 7BN United Kingdom
EC AUTHORISED REPRESENTATIVE:	Ortho-Clinical Diagnostics 1500 Boulevard Sébastien Brant B.P. 30335, 67411 Illkirch CEDEX, France
PRODUCT AND PRODUCT CODE(S):	Ortho® BLISS (10 mL) - 6902040 Ortho® BLISS (50 mL) - 707116
CLASSIFICATION:	Non-Annex II/ General/ GIVD (others)
CONFORMITY ASSESSMENT ROUTE:	Annex III

Ortho-Clinical Diagnostics is declaring that the *in vitro* diagnostic medical devices listed above comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices, the UK Medical Devices Regulations 2002, No: 618. All supporting documentation is maintained by Millipore UK Ltd.

STANDARDS APPLIED:

- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- EN ISO 23640:2015 In vitro diagnostic medical devices -- Evaluation of stability of in vitro diagnostic reagents
- EN 13612:2002 Performance Evaluation of in vitro diagnostic medical devices

- **DECLARATION OF CONFORMITY *(continued)***

STANDARDS APPLIED *(continued):*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic reagents
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)- Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)- Part 2: In vitro diagnostic reagents for professional use
- EN ISO 15223-1:2016 Symbols for use in the labelling of medical devices
- EN ISO 13485: 2016 - Medical devices. Quality management systems. Requirements for regulatory purposes.

DATE OF ORIGINAL CE-MARKING: April 2003

Name: Richard Saunders
Place: Pencoed, UK
Title: Technical Director, International Regulatory Affairs

2021/08/15
Date: (year/month/day)