

Ortho Clinical Diagnostics

ATITIKTIES DEKLARACIJA

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| GAMINTOJAS: | Ortho-Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5 PZ Jungtinė Karalystė |
| GAMYBOS ATSTOVAS: | Millipore UK Ltd. Fleming Rd. Kirkton Campus Livingston EH54 7BN Jungtinė Karalystė |
| CE ĮGALIJOTAS ATSTOVAS: | Ortho-Clinical Diagnostics 1500 Boulevard Sebastien Brant B.P 30335 67411 Illkirch CEDEX, Prancūzija |
| PRODUKTAS IR PRODUKTO KODAS: | Ortho BLISS (10 ml) – 6902040 Ortho BLISS (50 ml) – 707116 |
| KLASIFIKACIJA: | Ne-priedas II/bendras/GIVD (kita) |
| ATITIKTIES VERTINIMO BŪDAS: | Priedas III |

Ortho-Clinical Diagnostics pareiškia, kad aukščiau išvardyti in vitro diagnostikos medicinos prietaisai atitinka Direktyvos 98/79/EB dėl in vitro diagnostikos medicinos prietaisų, JK medicinos prietaisų reglamento 2002 m., Nr. 618. Visi patvirtinamieji dokumentai yra jo kontroliuojami Millipore UK Ltd.

TAIKOMI STANDARTAI:

- 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

- 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.

ORIGINALI CE ŽENKLINIMO DATA: 2003 m. balandis



Name: Richard Saunders

Place: Pencoed, UK

Title: Technical Director, International Regulatory Affairs

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