

Ortho Clinical Diagnostics

ATITIKTIES DEKLARACIJA

Gamintojas: Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester
New York 14626
JAV

Įgaliotas atstovas: Ortho-Clinical Diagnostics
Felindre Meadows
Pencoed
Bridgend CF35 5PZ
Didžioji Britanija
Arba
Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant,
B.P. 30335,
67411 Illkirch,
CEDEX,
Prancūzija

Ortho-Clinical Diagnostics pareiškia, kad žemiau išvardinti in vitro diagnostiniai medicinos prietaisai atitinka Direktyvos **98/79/EC** sąlygas, taikomas In Vitro diagnostiniams medicinos prietaisams, bei JK Medicinos prietaisų nuostatus **2002** Nr. 618.

Produkto pavadinimas: *VITROS Cheminis produktas 7%Galvijų serumo albuminas*

Produkto kodas: 8262487

Klasifikacija: Priedas III

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ATITIKTIES DEKLARACIJA (*tęsinys*)

TAIKOMI STANDARTAI:

- EN ISO 14971: 2012 Medical devices — Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 23640:2015 In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
- EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN ISO 17511:2003 In vitro diagnostics systems — Measurement of quantities in samples of biological origin — Metrological traceability of values assigned to calibrators and control materials.

Originalaus CE ženkinimo data:

2003-06-17



(parašas)

2019-7-23
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