

# Ortho Clinical Diagnostics

Ortho-Clinical Diagnostics pareiškia, kad toliau išvardyti in vitro diagnostikos medicinos prietaisai atitinka Direktyvos 98/79/EB dėl in vitro diagnostikos medicinos prietaisų, JK medicinos prietaisų reglamentų 2002 m. Nr. 618, Prancūzijos potvarkio Nr. 2001 nuostatas. -198 ir 2009 m. lapkričio 27 d. Komisijos sprendimas 2009/886/EB dėl in vitro diagnostikos medicinos prietaisų bendrųjų techninių specifikacijų. Gamintojas yra visiškai atsakingas už atitikties deklaracijos išdavimą, o visus patvirtinamuosius dokumentus jis kontroliuoja.

## ATITIKTIES DEKLARACIJA

**GAMINTOJAS:**

Ortho-Clinical Diagnostics  
Felindre Meadows  
Pencoed  
Bridgend  
CF35 5PZ  
Jungtinė Karalystė

**GAMYBOS PAGRINDAS:**

Ortho-Clinical Diagnostics  
Felindre Meadows  
Pencoed  
Bridgend  
CF35 5PZ  
Jungtinė Karalystė

**EB ĮGALIOJOTASIS ATSTOVAS:**

Ortho-Clinical Diagnostics  
1500 Boulevard Sebastien Brant  
B.P 30335, 67411 Illkirch  
CEDEX, Prancūzija

**PRODUKTAS:**

Ortho BioVue System Blood Group Reagents:

# Ortho Clinical Diagnostics

Produkto kodas	Sutrumpintas pavadinimas	Produkto pavadinimas
707150, 707190	ABO-Rh Grouping Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-CDE (Anti-RH1,2,3) (Monoclonal) Control Ortho BioVue® System (ABO-Rh Grouping Cassette)
707250, 707280	Rh/K Cassette	Blood Grouping Reagents Anti-C (Anti-RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti- $\bar{c}$ (Anti-RH4) (Monoclonal) Anti-e (Anti-RH5) (Monoclonal) Anti-K (Anti-K1) (Monoclonal) Control Ortho BioVue® System (Rh/K Cassette)
707255	Rh-hr Cassette	Blood Grouping Reagents Anti-D (Anti-RH1) (Monoclonal) Anti-C (Anti-RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti- $\bar{c}$ (Anti-RH4) (Monoclonal) Anti-e (Anti-RH5) (Monoclonal) Control Ortho BioVue® System (Rh-hr Cassette)
707100, 707155	ABO-Rh/Reverse Grouping Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette)
707135	ABD Confirmation Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Ortho BioVue® System (ABD Confirmation Cassette)
6904485	ABD Confirmation Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Ortho BioVue® System (ABD Confirmation Cassette)

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Produkto kodas	Sutrupintas pavadinimas	Produkto pavadinimas
6901906	Newborn Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Anti-Human Globulin Anti-IgG (Rabbit) (Green) Ortho BioVue® System (Newborn Cassette)
707270	ADK Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-K (Anti-K1) (Monoclonal) Control Ortho BioVue® System (ADK Cassette)
707550, 707580	Reverse Diluent Cassette	Reverse Diluent Ortho BioVue® System (Reverse Diluent Cassette)
707119	ABO-DD Grouping Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Ortho BioVue® System (ABO-DD Grouping Cassette)
707117	K Cassette	Blood Grouping Reagent Anti-K (Anti-K1) (Monoclonal) Ortho BioVue® System (K Cassette)
6986736	ABD/Reverse Cassette	Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Reverse Diluent Ortho BioVue® System (ABD/Reverse Cassette)

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**KLASIFIKACIJA:** II priedas, A sąrašas

**ATITIKTIES VERTINIMO BŪDAS:** Priedas IV

## 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 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic reagents
- EN 13612:2002 Performance Evaluation of in vitro diagnostic medical devices
- 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
- BS 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
- BS EN ISO 13485: 2016 - Medical devices – Quality management systems - Requirements for regulatory purposes.

## ŽYMĖJIMO ĮSTAIGA:

TÜV SÜD Product Service GmbH  
Zertifizierstelle  
Ridlerstraße 65  
80339 Münchenas  
Vokietija

**ŽYMĖJIMO ĮSTAIGOS NUMERIS:**

0123

**ORIGINALI CE ŽENKLINIMO DATA:**

2002 m. Liepa

**CE PROJEKTO TYRIMO SERTIFIKATAS:**

V7 071279 0046 Perž. 02

**CE SERTIFIKATAS:**

V7 071279 0041 Perž. 02



**Name:** Richard Saunders

**Place:** Pencoed, UK

**Title:** Technical Director, International Regulatory Affairs



**Date:** (year/month/day)