Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Ortho-Clinical Diagnostics is declaring that the *in vitro* diagnostic medical devices listed below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices, the UK Medical Devices Regulations 2002, No: 618, the French Ordinance No. 2001-198 of March 2001 The manufacturer has the sole responsibility for issuance of the declaration of conformity and all supporting documentation is retained under their control.

Manufacturer:	**Ortho-Clinical Diagnostics** Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom
Authorized Representative:	**Ortho-Clinical Diagnostics** 1500 Boulevard Sébastien Brant B.P. 30335, 67411 Illkirch CEDEX, France
Manufacturing Facility:	Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ08869 U.S. A

PRODUCT: Reagent Red Blood Cells

Product Code	Product Name
719602	0.8% Selectogen®
719102	0.8% Surgiscreen®
719502	0.8% Resolve® Panel A
719522	0.8% Resolve® Panel B

CONTRACT MANUFACTURING FACILITIES:

Product Code	Product Name	Etablissment Francais Du Sang (EFS)
719602 719102	0.8% Selectogen® 0.8% Surgiscreen®	Centre-Pays de la Loire 34 Boulevard Jean Monnet BP 91115 - 44011 Nantes Cedex 01, FRANCE
719102	0.8% Surgiscreen®	Paca-Corse 149 Boulevard Baille 13392 Marseille Cedex 05 FRANCE
719102 719502	0.8% Surgiscreen® 0.8% Resolve® Panel A	Grand EST 45, rue Cognacq-Jay 51 100 Reims FRANCE

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

CLASSIFICATION:	Annex II List B
CONFORMITY ASSESSMENT ROUTE:	Annex IV

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 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
- EN 980:2008 Symbols for use in the labelling of medical devices
- BS EN ISO 13485:2016 Medical devices – Quality Management Systems- Requirements for Regulatory Purposes
- 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

NOTIFIED BODY:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München Germany
NOTIFIED BODY NUMBER:	0123
DATE OF ORIGINAL CE-MARKING:	July 2002
EC CERTIFICATE:	V1 071279 0041 Rev. 02

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

2022/04/08
Date: (year/month/day)