

# Ortho Clinical Diagnostics

## DECLARATION OF CONFORMITY

**MANUFACTURER:** Ortho-Clinical Diagnostics  
Felindre Meadows  
Pencoed  
Bridgend  
CF35 5PZ  
United Kingdom

**MANUFACTURING FACILITY:** Ortho-Clinical Diagnostics, Inc.  
1001 US Highway 202  
Raritan, NJ 08869  
U.S.A.

**EC AUTHORISED REPRESENTATIVE:** Ortho-clinical Diagnostics  
1500 Boulevard Sébastien Brant  
B.P. 30335, 67411 Illkirch  
CEDEX, France

### PRODUCT AND PRODUCT CODE(s):

Name	Product Code
Affirmagen® – A1, B 1 x 3ml	707930
Affirmagen® 4 – A1, A2, B, O 1 x 3ml	707910

### CONTRACT MANUFACTURING FACILITY:

Etablissement Francais Du Sang  
(EFS) PACA-CORSE  
149, Boulevard Baille  
13392 Marseille Cedex-05  
FRANCE

### PRODUCT AND PRODUCT CODE:

Name	Product Code
Affirmagen® - A1, B 1 x 3ml	707930

**CLASSIFICATION:** Annex II List A

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## DECLARATION OF CONFORMITY *(continued)*

### CONFORMITY ASSESSMENT

#### ROUTE:

Annex IV

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 the French Ordinance No. 2001-198 of March 2001 and commission decision 2009/886/EC of 27 November 2009 on Common Technical Specifications for In-Vitro Diagnostic Medical Devices. The manufacturer has the sole responsibility for issuance of the declaration of conformity and all supporting documentation is retained under their control.

#### 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
- 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.

#### NOTIFIED BODY:

TÜV SÜD Product Service GmbH  
Zertifizierstelle  
Ridlerstraße 65  
80339 München  
Germany

#### NOTIFIED BODY NUMBER:

0123

#### DATE OF ORIGINAL CE-MARKING:

OCT 2002

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## DECLARATION OF CONFORMITY *(continued)*

**EC DESIGN EXAMINATION  
CERTIFICATE:**

V7 071279 0044 Rev.01

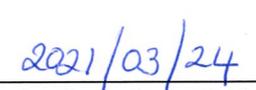
**EC CERTIFICATE:**

V1 071279 0041 Rev.01

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**Name:** Richard Saunders

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

**Place:** Pencoed, UK

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