

Declaration of Conformity

Manufacturer: International Medical Research Pty Ltd
Address: Unit 5, 10 Whipple Street, Balcatta, WA 6021, Australia.

European Representative (AR): Wellkang Ltd
Address: Wellkang Ltd, Enterprise Hub,
NW Business Complex, 1 Beraghmore Rd.,
Derry, BT48 8SE, Northern Ireland, UK

Product: Name: Closed Wound Drainage Systems
Types: Drainage Tube Series; CWV (Closed Wound Vacuum) Drain series; CWV
Reservoirs.

Classification: IIa, rule 7 according to annex IX of the MDD

Conformity assessment Route: Annex II excluding section 4

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:

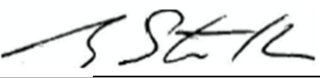
EN 1617:1997, EN ISO 10993-1:2009, ISO10993-7: 2008, EN ISO11135-1:2007,
EN 556-1:2001, EN ISO 11607-1:2009, IEC 62366:2007, EN ISO13485:2016,
EN ISO14971:2012, EN 980:2008, EN 1041:2008, EN 14644-1:2015, ISO 11737-1:2018,
ISO 11737-2:2009, EN ISO 11737, MDD 93/42/EEC, MDR 2017/745 – 5 April 2017,
ISO/TR 24971, MEDDEV 2.7/1 Revision 4 - 2016

Notified Body: **MEDCERT GmbH**
Address: Pilatuspool 2, 20355 Hamburg, Germany
Identification number: 0482

(EC) Certificate(s):

Products covered: Refer attached.
Place & Date of Issue: Hamburg, 1st April 2020

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex certificate issued by the notified body.

Signature:  23/07/2021

Name/position: Ray Stubber - Managing Director