

DECLARATION OF CONFORMITY

Product: HYDR/IM C61WD G4 Instrument Washer-Disinfector

Models: C61WD-D02, C61WD-D04, C61WD-D11

Classification: Class IIa (MDD Annex IX, Rule 15)

Manufacturer: SciCan Ltd.

Manufacturer Address: 1440 Don Mills Road Telephone (416) 445-1600
Toronto, Ontario Fax (416) 445-2727
M3B 3P9 Canada

European Representative: SciCan GmbH
Wangener Straße 78
88299 Leutkirch, Germany

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards and that SciCan Ltd. has exclusive responsibility for the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer's premises.

DIRECTIVE

General Applicable Directive:

Medical Devices Directive: Council Directive 93/42/EEC of June 14 1993 concerning medical devices [MDD 93/42/EEC, Annex II, excluding (4)].

Standards:

Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are:

EN 61010-1:2001; EN 61010-2-040:2005; ISO 15883-1:2006; ISO 15883-2:2006; ISO 13485:2016; EN ISO 14971:2012; EN 980:2008; EN 62304:2006

This product also complies with: **EN 61326-1:2013.**

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraß 65,
D-80339 München, Deutschland
Identification No. 0123

Certificate: G1 17 08 12160 057

Date CE Mark was affixed: March 25, 2013

Date of Effectiveness of Product Under this Declaration: March 13, 2018

Place: Toronto, Canada

Signature:



Date:

MARCH 13, 2018

Name & Title: John Westermeier, CEO