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OHIRA Co., Ltd.

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EC DECLARATION OF CONFORMITY

(No.DC-S05-H)

Manufacturer: Ohira Co., Ltd.

European Representative: Fausto Guzzetti
(Shin-Nippon Technical Center)
Via Solferino, 5 21057 Olgiate Olona(VA), Italy

Product: Trade Name: LED SLIT LAMP XL-1
Description: Slit Lamp

Classification: Class I without measuring function
Rule 12 according to Annex IX of the MDD

Conformity Assessment Route: Annex VII applied

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC
(MDD 93/42/EEC)

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

EN ISO 15004-1:2009	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)
EN 60601-1:2006/+A1:2013	Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:2005/+A1:2012)
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014)
EN ISO 10993-1:2009 /AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

This declaration of conformity is valid from January 10,2019. (Valid from SN. 2019-3022)

Signature:

Name Takahiro Ohira

Position Manager of engineering department

Date: 2019.1.10