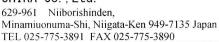
## 株式会社 オーヒラ

〒949-7135 新潟県南魚沼市新堀新田629-961

OHIRA Co., Ltd.





Date: Aug 9, 2017

## EC DECLARATION OF CONFORMITY

(No.DC-S441-B)

Manufacturer:

Ohira Co., Ltd.

**European Representative:** 

Fausto Guzzetti

(Shin-Nippon Technical Center)

Via Solferino, 5 21057 Olgiate Ólona(VA), Italy

**Product:** 

Trade Name: SLIT LAMP SL-203

**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	Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:2005)
EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007)
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)

Signature:

Position Manager of engineering department