EU DECLARATION OF CONFORMITY

In accordance with Article 19 and Annex IV of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Manufacturer: **RIMSA P. LONGONI S.r.l.**

Address of registered place of business: Via Monterosa, 18/20/22 – 20831 SEREGNO (MB) – ITALY

Single registration number (SRN): not yet issued by the competent authority

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Device identification: LUMINAIRE FOR DIAGNOSIS

Basic UDI-DI	**Device code**	**Device name**
++B880ALFAFIXSJ	ALFA-FIX	LAMP MODEL ALFA-FIX
++B880ALFAFLEXV7	ALFA-FLEX	LAMP MODEL ALFA-FLEX
++B880L88LEDMMA	L88-LED-M	LAMP MODEL L88-LED MEDICAL
++B880PRIMAFIXD3	PRIMA-FIX	LAMP MODEL PRIMALED JOINTS ARM
++B880PRIMAFLEXMA	PRIMA-FLEX	LAMP MODEL PRIMALED-FLEX

Risk class of the device in accordance with the rules set out in Annex VIII of REGULATION (EU) 2017/745: **CLASS I**

Explanation: Duration: Short term (Annex VIII, CHAPTER I, point 1. DURATION OF USE)

Description: Non-invasive medical device (Annex VIII, CHAPTER III, point 4. NON-INVASIVE DEVICES, par. 4.1 Rule 1)

Active medical device (Annex VIII, CHAPTER III, point 6. ACTIVE DEVICES, par. 6.2 Rule 10)

The manufacturer declares that the medical device is in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and with the following standards:

- IEC 60601-1 (Part 1: General requirements for basic safety and essential performance)
- IEC 60601-1-2 (Part 2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)
- IEC 60601-2-41 (Part 1: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis)

The conformity assessment procedure is developed with reference to premise (60) and Article 52 of REGULATION (EU) 2017/745.

RIMSA Quality System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards and is certified by CSQ (CSQ certificate no. 9120.RMS1 and 9124.RMS2).

Seregno, 26/05/2021

Place and date

Mark and sign of Managing Director
(Paolo Longoni)