



## **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: MINOR SURGICAL LUMINAIRE

Basic UDI-DI	Device code	Device name
++B880PENTA12PAAD	PENTA12PA	LAMP MODEL PENTALED 12 WALL
++B880PENTA12PIAV	PENTA12PI	LAMP MODEL PENTALED 12 MOBILE STAND
++B880PENTA12SOBJ	PENTA12SO	LAMP MODEL PENTALED 12 CEILING
++B880PENTA12126P	PENTA12+12	LAMP MODEL PENTALED 12 DOUBLE CEILING

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)