RIMSA

MANUFACTURER'S DECLARATION OF CONFORMITY CE

The company **RIMSA P. LONGONI S.r.l.**
Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) - ITALY

declares on its own responsibility that the Medical Devices made in the year 2019:

Model: **ALFA-LED**

constructed by RIMSA P.LONGONI S.r.l., conforms:

- *to the Attachment VII of the 93/42/EEC Directive of May 14th 1993, and subsequent variations (including the 2007/47/EC Directive of September 5th 2007); moreover, it is in conformity with the following safety regulation:*

  - IEC 60601-1 (Part 1: General requirements for basic safety and essential performance)
  - IEC 60601-2-41 (Part 2: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis)
  - IEC 60601-1-2 (Part 1: General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility - Requirements and tests)

  - Classification with reference to article 9 and Attachment IX of 93/42/EEC Directive and 2007/47/EC
    Duration : Short term (Annex IX, Par.1 "Definitions", art.1, sub-section 1.1)
    Description: Non invasive Medical Device (Annex IX, Par.1 "Definitions", art.1, sub-section 1.2)
    Active Medical Device (Annex IX, Par.1 "Definitions", art.1, sub-section 1.4)
    Class: Class I (Annex IX, Par.3 "Classification", art.3, sub-section 3.3, Rule 12)
    (Annex IX, Par.3 "Classification", art.1, sub-section 1.1, Rule 1)
  - Reference to technical file Code RIM-FT015.
  - The conformity assessment is developed in reference to article 11 of the 93/42/EEC Directive and 2007/47/EC .

The RIMSA Quality System conforms to the UNI EN ISO 9001 and UNI EN ISO 13485 regulations and is certified by the CSQ (certified CSQ n.9120.RMS1 and 9124.RMS2).

RIMSA P.LONGONI S.r.l.

Seregno, 07/01/2019

Place and date

Mark and sign of Managing Director
(Paolo Longoni)

COPIA CORESPUNDE ORIGINALULUI