

DECLARATION OF CONFORMITY EC

MANUFACTURER: INMED-Karczewscy Sp. z o.o. Sp. k
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PRODUCTS: **Surgical Luminaire LISSAled-set**

CLASSIFICATION: Class I, Rule 12, according to Annex IX MDD 93/42/EEC

I declare that I will supervise the proper application of the quality management system dedicated to design, production and final inspection of the medical equipment specified above. I assure and declare that the aforementioned products meet requirements of Medical Device Directive 93/42/EEC and that I own the technical file proving the performance of the products conformity assessment related to directive mentioned above. Assessment of conformity was carried out according to the procedure of Annex 7 of Directive 93/42/EEC.

This declaration of conformity is the basis for labelling of products with the CE mark.

APPLIED STANDARDS: EN 1041:2008, EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 62366-1:2015, EN ISO 9001:2015, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN ISO 7010:2012, EN 62471:2008, EN 60601-2-41:2009, EN 62304:2006, EN 62133:2013

CERTIFICATES: PN-EN ISO 9001:2015 nr AC090 100/1961/4999/2020
PN-EN ISO 13485:2016-04 nr AC090 MD/1961/4999/2020

May, 2020
Krępiec, Poland

Tomasz Czarnecki



President of the Board of INMED-Karczewscy Sp. z o.o. Sp.k.