

UE DECLARATION OF CONFORMITY

INMOCLINC, S.L.U.

B88601893

SINGLE REGISTRATION NUMBER (SNR): ES-MF-000000291

C/ SERRANÍA DE CUENCA, 10

POL. IND. "EL OLIVAR"

28500 ARGANDA DEL REY. MADRID

D. Ángel Moreno González, General Manager of INMOCLINC, S.L.U., Industry of Clinical furniture, issues this Declaration of Conformity under the sole responsibility of the distributor, and

DECLARES

Comercial Name:	Minor surgery and examination lamp
Family:	Lamps
Risk Class:	Medical Device Class I
Referce:	20095
UDI-DI:	8435562860387

It is in responsibility for compliance with the requirements of the Regulation (EU) 2017/745, of April 5, 2017, on medical devices, in compliance with article 19, and, and Royal Legislation 1591/2009, of October 16, which regulates medical devices, thus guaranteeing the absence of commitment to the health and safety of persons, provided that the product is used according to its purpose, as well as offering benefits assigned.

- UNE-EN 60601-1:2008+A12:2015 Part 1 Medical equipments
- UNE-EN 60601-1-2:2015 Part 2 Medical equipments
- UNE-EN 60601-2-41:2010+A111:2012+A1:2015

COMMITTS. To establish and maintain a systematical procedure to review experience gained from devices in the post-production phase, using the appropriate means to implement the necessary corrective measures. Likewise,

COMMITTS: To inform the competent authorities on the following facts as soon as it becomes aware of them:

- a) Any malfunction or alteration of the features or benefits, as well as any inadequacy of labeling or instructions for use of a product that might, or might have given rise to the death or serious disruption of the health status of a patient or a user;
- b) Any reason for technical or medical linked to the characteristics and performance of a device for the reasons stated in the preceding paragraph that has led the manufacturer to systematically withdraw from the market products that belong to the same type.

Date: On May 21, 2021



INMOCLINC, S.L.U.
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(Madrid)

Signature: D. Ángel Moreno González
General Manager