

UE DECLARATION OF CONFORMITY

INMOCLINC, S.L.U. B88601893

Nº REGISTRO ÚNICO (SNR): ES-MF-000000291

C/ SERRANÍA DE CUENCA, 10 POL. IND. "EL OLIVAR"

28500 ARGANDA DEL REY. MADRID

Mr. Ángel Moreno González, General Manager of INMOCLINC, S.L.U., Industry of Clinical furniture, DECLARES under its responsibility that the medical device, distributed by INMOCLINC, S.L.U., with the following identification:

Comercial Name:	Wall mounted X-Ray viewer, two screen, epoxy
Family:	X-Ray viewer
Risk Class:	Class I according to rule 1 of Annex VIII to the MDR (UE) 2017/745
Referencia:	16103
UDI-DI Básico	8424591NGVH
UDI-DI:	8424591NG6002MJN

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 Royal Decree 1591/2009, of October 16, which regulates medical devices, Directive 2014/35/EC on Low Voltage, Directive 2014/30/EC on electromagnetic compatibility, Directive 2011/65/EU on the use of certain hazardous substances in electrical and electronic equipment, and complies with the following rules:

UNE-EN 60601-1:2008+A12:2015 Part 1 Medical electrical equipment

UNE-EN 60598-1:2015+A1:2018 Part 1 Luminaires Part 2 Luminaires UNE-EN 60598-2-1:1993

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.

INMOCLINC, S.L.U. issues this Declaration of Conformity under the information provided by the manufacturer.

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

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

- 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;
- 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 June 01, 2022

28500 Arganda del Rey (Madrid) Signature: D. Ángel Moreno González

Pol. Ind. El Olivar

General Manager