

EU DECLARATION OF CONFORMITY

(Conformity according to Regulation (EU) 2014/35/EU, 2014/30/EU and 2011/65/EU)

PRODUCT IDENTIFICATION

ELEMENT: DESCRIPTION

Product name:	Premium Box, Premium Box 2, Premium Box 3 (A612099-635; A612099-638; A612099-6383)
Product description:	Connectivity hub for Labomed Prima Premium microscopes. Provides USB, HDMI, Wireless HDMI, and power distribution.
Model / Type:	Premium Box (internal PCB with HDMI splitter, USB hub, wireless HDMI transmitter)
Power input:	5 V DC (supplied by external MeanWell GSM40A05-P1J medical power adaptor, or other similar product)
Intended use:	To interface microscope camera signals (USB/HDMI) to external displays or computer equipment. Internal distribution of power and signals.
Configuration:	Assembly of CE-certified components (USB hub, wireless HDMI transmitter, HDMI splitter, wiring harness).

APPLIED HARMONISED STANDARDS

No.	Standard reference	Title / Scope
1	EN 62368-1:2020 (or EN 62368-1:2014 if required)	Safety requirements for audio/video and ICT equipment
2	EN 55032:2015 + A1:2020	EMC – Multimedia equipment – Emission
3	EN 55035:2017 + A1:2020	EMC – Multimedia equipment – Immunity
4	EN IEC 61000-3-2:2019	EMC – Harmonics
5	EN IEC 61000-3-3:201	EMC – Voltage fluctuations and flicker
6	EN 50581 / EN IEC 63000:2018	RoHS technical documentation

COMPONENTS USED INSIDE THE PREMIUM BOX CARRY THEIR OWN CONFORMITY:

Article codes: A612099-623, A612099-624, A612099-472, A612099-619, A612099-484, P612099-100, A612099-615, A612099-620, A612099-626, P612099-110, A612444-001, A612099-653 and A612099-576

These certificates are included in the Technical Documentation File (Annex).

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TRACEABILITY / MANUFACTURING

The product is manufactured under the sole responsibility of:

Labomed Europe B.V.
Essebaan 50
2908 LK Capelle aan den IJssel,
The Netherlands

The complete technical file has been compiled and will be made available to European market authorities upon request.

DECLARATION

This declaration is issued under the sole responsibility of the manufacturer. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation.



P.J. Timmermans
Founder of Labomed Europe

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