LABOMED

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CE

EU DECLARATION OF CONFORMITY

CE

Labo America

Declare under sole responsibility that

Our medical devices: Accessories Surgical Microscopes

Models: Assistoscope/ Beam Splitter, / Camera Adapter/Extender Wedge/Roto Plate/ Vesa Mount/ Pico conversion Kit/ Double Iris Diaphram Kit/ Endo Adapter/ Monitor Arm For Magna

Model Nos.: 6134117/6134150,6134152,6134160,6134162,61225001,6319051,6122500/ 6134110,6134131C,6134131N,6134131S,6134132C,6134132S,6134120,6134171/6134165/6134115-801/ 6137500-800/6137600,6137650/6214051/6134180/6129001-876,6129000-877

Basic UDI-DI 81017855ACCESSORIESSLIT7C

Are intended for use in photo documentation on a surgical microscopes during diagnosis and surgery to provide a magnified view of examination of the region of interest

Have been subjected to conformity assessment procedure complying with Article 52 (7) and technical documentation accordance to Annexure II and III of council regulation (EU) 2017/745.

These Devices are Class 1 (without a measuring function,non active and non invasive) per Rule 1 annex VIII of the regulation MDR 2017/745

Labo America designs and manufactures all products under Quality Systems registered to meet the requirements of ISO 9001, ISO 13485, 21CFR 820 and MDR 2017/745. In case of alteration of the device, not agreed upon by us, this declaration will lose its validity.

Applied harmonized standards, national standards and other normative documents:

EN/ISO: 15223-1 EN
EN /IEC 60601-1-1
EN/ISO: 14971

EN/ISO: 10936
EN 62366

AUTHORIZED SIGNATORY

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EC REP

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