

**EU DECLARATION OF CONFORMITY****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 Diaphragm Kit/ Endo Adapter/ Monitor Arm For MagnaModel Nos.: 6134117/6134150,6134152,6134160,6134162,6122501,6319051,6122500/  
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 interestHave 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 2017/745Labo 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: 14971EN/ISO: 10936  
EN 62366**AUTHORIZED SIGNATORY**Gautam Aggarwal  
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