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## EU DECLARATION OF CONFORMITY



**Labotech Microscopes India Pvt.Ltd.**  
Declare under sole responsibility that

**Our medical devices: Surgical Microscopes For Otolaryngology**

**Models : Prima Mu ENT /Prima ENT ,Prima Swift (Floor, Wall & Ceiling Mount)  
Basic UDI-DI 8908006463621-MU-ENTN2 / Basic UDI-DI 8908006463613-PR-ENTNP  
Model NOS: 6212000 / 6137000,6137000-100 ,6182501,6182502,6182503**

**Are AC powered devices intended for use in Otolaryngology during diagnosis and surgery to provide a magnified view 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) per Rule 13 annex VIII of the regulation MDR 2017/745**

**Labotech designs and manufactures all products under Quality Systems registered to meet the requirements of 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.**

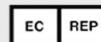
**Applied harmonized standards, national standards and other normative documents:**

EN/ISO: 15223-1  
EN /IEC 60601-1  
EN/ISO: 14971  
EN/ISO: 10936  
EN 62366

EN 61010-1  
EN/IEC 61326-1  
EN/IEC 61000-3-3  
EN/IEC 61000-3-2  
CISPR11/EN 55011

**AUTHORIZED SIGNATORY**

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