LABOMED

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CE

EU DECLARATION OF CONFORMITY

CE

Labo America

Declare under sole responsibility that

Our medical devices: Colposcopes

Models: eVA 500/ Prima GN, Prima C, Prima CS
REF Nos.: 6169000,6169200/6165000,6128000,6128600

Basic UDI-DI 81017855GNSURGICALFR

Are AC powered devices intended to provide magnified view of the tissues of the vagina and cervix by a telescopic system located outside the vagina.it is used to diagnose abnormalities and select areas for biopsy.

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

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 /IEC 60601-1-2
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 5501

AUTHORIZED SIGNATORY

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EC REP

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