



EC DECLARATION OF CONFORMITY

Labotech microscopes India (pvt) Ltd.
19 HSIDC Industrial Estates, Ambala Cantt – 133006.Haryana, INDIA

Declare under sole responsibility that

Our medical device: **Surgical microscopes**
Models: **Prima OPH, Prima ENT, Prima DNT, Prima GN, eVA500, eVA500D, eVA500G**

Are in conformity with the essential requirements and
of council directive for safety

Class 1 (without a measuring function) per Rule 12 annex IX

Compliance with Medical Device Directive MDD 93/42/EEC annex II (excluding section 4) as Amended
by Directive 2007/47/EC to meet provisions of IEC 60601-1-3rd ed.

LABOTECH manufacture its products under its Quality Systems registered to meet the requirements of
ISO 9001:2008, ISO 13485:2003, 21CFR 820 and Directive (MDD 93/42/EEC & 2007/47/EC). In case of
alteration of the machine, not agreed upon by us, this declaration will lose its validity.

Year of CE marking authorization: 2012
Notified Body: UL India

Applied harmonised standards, national standards or other normative documents:

EN 980: 2008
EN/ISO: 10993-1
EN/ISO: 14971-2009
EN/ISO: 10936
EN 62366:2008
EN /IEC 60601-1- 3rd ed

EN 61010-1:2001
EN/IEC 61326-1:2006
EN/IEC 61000-3-3:2008
EN/IEC 61000-3-2:2006
CISPR11:2010/EN 55011:2007

AUTHORIZED SIGNATORY

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