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BAUSCH & LOMB European Communities Council Directive 93/42/EEC Concerning Medical Devices

DECLARATION OF CONFORMITY
In accordance with Annex II
Certificate No.: <u>TF-003</u>

Bausch & Lomb Surgical, being the manufacturer/distributor within the European Economic Area declares that the products named on this certificate meet the provisions of the Council Directive Annex I which apply to them and the CE mark may be affixed.

General Product Name: Millennium Microsurgical System

Manufacturer:

Bausch & Lomb

3365 Tree Court Ind. Blvd St. Louis, MO 63122 USA

European Representative:

Bausch & Lomb, Inc.

Regent Park Kingston Road Leatherhead, KT22 7PQ UK

Intended Use: The Millennium Microsurgical System is intended for general uses in various anterior and posterior segment ophthalmic surgical procedures.

Directive Classification No.:

IIb

UMDNS:

N/A

Signed

Dennis Pozzo

Regulatory Affairs Specialist

Date