ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 13 05 27023 043

Manufacturer:

CROMA-PHARMA GmbH
Industriezeile 6
2100 Leobendorf
AUSTRIA

Facility(ies):

CROMA-PHARMA GmbH
Industriezeile 6, 2100 Leobendorf, AUSTRIA

Product Category(ies):

Viscoelastic solutions for intraocular, intraarticular and topical application;
Implantable ocular endotamponades;
Sterile cannulae for ophthalmic surgery;
Opthalmic surgical systems including accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713024667

Valid from: 2013-08-30
Valid until: 2018-08-29

Date, 2013-07-22

Hans-Heiner Junker

582699

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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