



Product Service

EC - CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 08 02 27023 040

Manufacturer: **CROMA-PHARMA Gesmbh**
Industriezeile 6
2100 Leobendorf
AUSTRIA

Facility(ies): CROMA-PHARMA Gesmbh
Industriezeile 6, 2100 Leobendorf, AUSTRIA

Product Category(ies): **Viscoelastic solutions for intra-articular and ophthalmic application. Implantable ocular endotamponades. Sterile cannulae for ophthalmic surgery.**

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 products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 71333226

Valid until: 2013-08-29

Date, 2008-08-30

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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