

EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-006

Issued to: PRIZMA Kragujevac d.o.o.
Kumanovska 8, 34000 Kragujevac, Serbia
Place of production: PRIZMA Kragujevac d.o.o.
Zorana Đinđića 13, 34000 Kragujevac, Serbia
Product category: Inhalation devices
GMDN: /

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:

OSV 01026/2014, 2014-11-24

OSV 00910/2014, 2014-10-28

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2009-11-12

Issue : 5/2014-11-27

Valid until: 2017-11-30



Director of SIQ

Igor Likar

