

EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II (4)
Certificate No. 1304-MDD-006

Issued to: PRIZMA KRAGUJEVAC DOO
Kumanovska 8, 34000 Kragujevac, Srbija

Place of production: PRIZMA KRAGUJEVAC DOO
Kumanovska 8, 34000 Kragujevac, Srbija

Classification: Class IIa

Name of product category: Inhalation devices

SIQ hereby declares that the above mentioned manufacturer fulfils the relevant provisions of the Directive 93/42/EEC of June 14, 1993 concerning medical devices, including all subsequent amendments, and that for the products listed in Addendum to this certificate Conformity Assessment Procedure Annex II (4), is executed by the Manufacturer in the accordance with the provisions of the mentioned Directive.

Audit report No.: OSV 00014/2011 od dana 2011-01-21

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 of June 14, 1993 concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2009-11-12

Issue : 02/2011-01-27

Valid until: 2014-11-12

Director of SIQ

Igor Likar



Slovenski inštitut za
kakovost in meroslovje
Slovenian Institute of
Quality and Metrology

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Addendum

The certificate is valid for the hereafter following products:

Name of product category: Inhalation devices

Name of individual type: Ultrasonic Nebuliser, Dry Salt Aerosol Generator for Inhalation

Classification: Class IIa

Model / Type reference: Ultrasonic Nebuliser PRIZMA MICROSONIC, Ultrasonic Nebuliser PRIZMA PROFISONIC, Dry Salt Aerosol Generator for Inhalation PRIZSALT

Certification date: 2009-11-12

Issue : 02/2011-01-27

Valid until: 2014-11-12



Director of SIQ

Igor Likar