Slovenski institut za kakovost in merosloviе
Slovenian Institute of Quality and Metrology

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

Slovenski institut za kakovost in merosloviе
Slovenian Institute of Quality and Metrology
Tržaška 2, 1000 Ljubljana
Slovenija / Slovenia
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Director of SIQ

Igor Likar

Slovenski institut za kakovost in merosloviе
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Directive 93/42/EEC on Medical Devices, Annex II (4)

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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

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