



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, Srbija

Place of production: PRIZMA Kragujevac d.o.o.
Zorana Đinđića 13, 34000 Kragujevac, Srbija

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 01070/2017, 2017-10-30
OSV 01025/2018, 2018-09-12
OSV 01238/2018, 2018-11-26
OSV 00503/2019, 2019-05-31
OSV 01176A/2019, 2019-10-30
OSV 01140/2019, 2019-12-10
OSV 00010/2020, 2020-03-09

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 : 07/2020-03-09

Valid until: 2024-05-27



Director of SIQ

Igor Likar



Z vami več kot
With you for over
50 let
years
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vaš znak / your ref.:

naš znak / our ref.:

datum / date:

OSV/2057

2020-03-09

Mr.
Mihajlo Miletić
PRIZMA Kragujevac d.o.o.
Kumanovska 8
34000 KRAGUJEVAC

Dear Mr. Miletić!

We would like to inform you that the Notified Body Commission for medical devices adopted the following decision at its last meeting:

On the basis of re-certification audit report and technical documentation audit report (OSV 01070/2017, dated on 2017-10-30), technical documentation post-audit report (OSV 01025/2018, dated on 2018-09-12), surveillance audit report, technical documentation audit report and post-audit report (OSV 01238/2018, dated on 2018-11-26), technical documentation post-audit report (OSV 00503/2019, dated on 2019-05-31), surveillance and re-certification audit report (OSV 01176A/2019, dated on 2019-10-30), technical documentation audit report (OSV 01140/2019, dated on 2019-12-10) technical documentation post-audit report (OSV 00010/2020, dated on 2020-03-09), the current edition (06/2017-11-27) of the EC certificate MDD-006 is cancelled and the new edition is issued:

EC certificate No.: **MDD-006**

Issued to: PRIZMA Kragujevac d.o.o.
Kumanovska 8, 34000 Kragujevac, Srbija

Place of production: PRIZMA Kragujevac d.o.o.
Zorana Đinđića 13, 34000 Kragujevac, Srbija

Product category: Inhalation devices

GMDN: /

Standard: MDD 93/42/EEC

Aneks/Annex: II

Kategorija proizvoda: Inhalatori

GMDN: /

Certification date: 2009-11-12

Issue: 07/2020-03-09

Valid until: 2024-05-27

Identification Number of the Notified Body (1304) can be used in conjunction with EC certificate. Details of affixing CE marking are given in Article 17 of Medical Device Directive (93/42/EEC).

The EC certificate (A4 paper format) is granted in English. EC certificate is enclosed in attachment. Also form for possible additional order of certificate is enclosed.

Detailed list of product names, models and types:

EC certificate No./ **MDD-006**
Br. EC sertifikata:
Issued to / PRIZMA Kragujevac d.o.o.
Naziv organizacije: Kumanovska 8, 34000 Kragujevac, Srbija
Place of production: PRIZMA Kragujevac d.o.o.
Zorana Đinđića 13, 34000 Kragujevac, Srbija
Product category / Inhalation devices/
Kategorija proizvoda: Inhalatori
GMDN: /
Classification / IIa
Klasifikacija:
Product name / PRIZMA ultrasonic nebulizer/
Naziv proizvoda: PRIZMA ultrazvučni inhalator
Alternative name / PROFI SONIC A, PROFI SONIC H-A, SonoDrop Profi
Alternativno ime:
Model/Type / PROFI SONIC, PROFI SONIC H
Model / Tip:

Product name / PRIZMA dry salt aerosol generator for inhalation/
Naziv proizvoda: PRIZMA inhalator za inhalaciju suvim prahom soli
Alternative name / HALOPRIZMA
Alternativno ime:
Model/Type / PRIZSALT+
Model / Tip:

Product name / PRIZMA compressor nebulizer/
Naziv proizvoda: PRIZMA kompresorski inhalator
Alternative name / /
Alternativno ime:
Model/Type / PRIZJet
Model / Tip:

Standard: MDD 93/42/EEC
Date of issuing the list / 2020-03-09
Datum izdaje seznama:
Valid until / 2024-05-27
Velja do:

For all further information we are available on telephone number 00 386 1 4778 159 and email: marjeta.tusek@siq.si

Management Systems Assessment
MDD Product Manager
Ana Pribaković Borštnik