



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 20 0303 QS/NB

The quality system of manufacturer

NewWaterMeaning s.r.o.

Pobřežní 249/46, 186 00 Praha 8, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

**Solutions for wound rinsing
Gels for Wound treatment**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2020-06-23

Valid until: 2024-05-27

First Issued: 2020-06-23

Revision: -



Date: 2020-06-23

Mgr. Jiří Heš

Representative of the Notified Body No. 1023



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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 20 0303 QS/NB

issued for manufacturer:

NewWaterMeaning s.r.o.
Pobřežní 249/46, 186 00 Praha 8, Czech Republic

Product(s):

Name: **DebriEcaSan Alfa**
Trade name(s): DebriEcaSan Alfa
Model(s): 30 ml, 115 ml, 500 ml, 500 ml push pull, 3 l container, 5 l container
Class: IIb
GMDN: 37298

Name: **DebriEcaSan aquagel**
Trade name(s): DebriEcaSan aquagel
Model(s): 30 g, 30 ml, 250 g, 500 g
Class: IIb
GMDN: 37298

Name: **DebriEcaSan hyal plus**
Trade name(s): DebriEcaSan hyal plus
Model(s): 115 ml, 250 ml
Class: IIb
GMDN: 37298

Name: **HyalEcaSan**
Trade name(s): HyalEcaSan
Model(s): 30 g, 50 g, 120 g
Class: IIb
GMDN: 37298

Date: 2020-06-23
Revision: -



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issued for manufacturer:

NewWaterMeaning s.r.o.
Pobřežní 249/46, 186 00 Praha 8, Czech Republic

Facility(ies):

NewWaterMeaning s.r.o.

Zlínská 155, 765 02 Otrokovice, Czech Republic (residence)

Zlínská 155, 765 02 Otrokovice, Česká republika (production plant)

Certificate History:

Revision	Date	Reference Number	Action
	2020-06-23	803602821	Certification process – conformity assessment

Date: 2020-06-23
Revision: -



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