

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 698761**

Issued To:

**Curasonix GmbH
Lübecker Str. 42,
Bad Schwartau
23611
Germany**

In respect of:

Design and manufacture of curason CSN ultrasonic wound cleaner and sterile accessories

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-04-29**Date: **2021-04-29**Expiry Date: **2024-05-26****...making excellence a habit.™**

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 698761

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1103 MD 0303	Curason Wound Cleaning Device	The medical device curason wound cleaning system is a hand-held device aimed at mechanically removing contaminated soft-tissue structures that might cause healing disturbances or infections.

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Page 2 of 2

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Heinz-Meise GmbH, Medizintechnik Im Gewerbepark 6, 58579 Schalksmühle, Germany	Gas Plasma Sterilization
Unitron Group B.V. Schansestraat 7 4515 RN IJzendijke The Netherlands	Manufacture
Unitron InnoTech B.V. Asveldweg 2, 7556 BP Hengelo The Netherlands	Design Development

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Certificate History

Certificate No: **CE 698761**
 Date: **2021-04-29**
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Date	Reference Number	Action
Current	9641656	First issue

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Page 1 of 1

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