

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 573748****Issued To:**

Henke-Sass, Wolf GmbH
Keltenstraße 1
78532 Tuttlingen
Germany

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2016-06-27**

Date: **2020-03-23**

Expiry Date: **2024-05-26**

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Page 1 of 3

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.

Certificate No: CE 573748

Certificate Scope:

Manufacture of sterile single use syringes and needles.**Those aspects of Annex V concerned with securing and maintaining the sterility single use syringes.****Those aspects of Annex V related to metrology in the manufacture of sterile and non-sterile single use syringes.****Herstellung von sterilen Einmalspritzen und Kanülen.****Die Aspekte im Zusammenhang mit Anhang V für die Herstellung von sterilen Einmalspritzen.****Die Aspekte im Zusammenhang mit Anhang V für die Herstellung von sterilen und nicht sterilen Einmalspritzen mit Messfunktion.**First Issued: **2016-06-27**Date: **2020-03-23**Expiry Date: **2024-05-26**

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Page 2 of 3

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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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Supplementary Information to CE 573748

Issued To:

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Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0102	Two and three part single-use syringes with detached or fixed needle, sterile	---
MD0102	Three part single-use syringes suitable for use with power driven syringe pumps, sterile	---
MD0102	Single use needles, sterile	---
Class Is, Im		
MD0104 MDS7006	Two and three part single-use syringes without needle; two part single-use syringe oral	---
Class Is		
MDS7006	Blunt Fill Needles	---
Class Im		
MD0104	Two and three part single-use syringes	---

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Page 3 of 3

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