By Royal Charter

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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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.

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Supplementary Information to CE 573748

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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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