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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2016-06-27** Date: **2017-07-30** Expiry Date: **2022-07-31**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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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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