By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 711081**

Issued To: **Ascensia Diabetes Care Holdings AG**
Peter Merian-Strasse 90
Basel
4052
Switzerland

In respect of:

Manufacture of single use sterile lancets and lancing devices for blood glucose management

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: **2019-09-04** Date: **2019-12-24** Expiry Date: **2024-05-26**

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Supplementary Information to CE 711081

Issued To:

Ascensia Diabetes Care Holdings AG
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1104	MICROLET NEXT lancing device	The MICROLET NEXT lancing device is used for obtaining capillary blood samples from the fingertip. Capillary samples can be obtained from the palm as well. The MICROLET NEXT lancing device is designed for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.
MD 0106	MICROLET lancet	The MICROLET Lancets are single use lancets intended for capillary blood sampling. The needle of the lancet is sterile and covered with a plastic cap, which is removed prior to the use of the lancet.

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