



# 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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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 711081

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1104	MICROLET NEXT lancing device	<p>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.</p> <p>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.</p>
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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