

## Declaration of Conformity

<b>LEGAL MANUFACTURER:</b>	<b>Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel Switzerland</b>
<b>PLACE OF MANUFACTURE (Lancets):</b>	<b>See page 2</b>
<b>PLACE OF MANUFACTURE (Lancing Devices):</b>	<b>See page 2</b>
<b>PRODUCT CATEGORY:</b>	<b>Lancet and Lancing Device</b>
<b>GMDN CODE:</b>	<b>Lancet: GMDN 45142 Lancing Device: GMDN 37243</b>
<b>PRODUCT:</b>	<b>Microlet Lancet</b>
<b>Used with</b>	<b>Microlet Next Lancing Device  Microlet2 Lancing Device Also sold as: Bayer Microlet2 Lancing Device</b>
<b>CLASSIFICATION:</b>	<b>Class IIa, Rule 6</b>
<b>CONFORMITY ASSESSMENT ROUTE:</b>	<b>Annex V of Directive 93/42/EEC applied</b>
<b>NOTIFIED BODY:</b>	<b>BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Country : Netherlands Notified Body number : 2797</b>
<b>EC CERTIFICATE NUMBER:</b>	<b>CE 711081</b>

We, Ascensia Diabetes Care Holdings AG, declare that the above-mentioned product(s) meet the provisions of

- the Council Directive 93/42/EC concerning Medical Devices
- the Directive 2006/42/EC Of The European Parliament And of The Council of 17 May 2006 on machinery, for the Lancing Devices.

The present EU Declaration of conformity is issued under sole responsibility of the manufacturer  
The Manufacturer retains all supporting documentation.

**2019-12-24  
Basel, Switzerland**



**Pam Schaub  
Head of Global Regulatory Affairs**

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**PLACE OF MANUFACTURE & PACKAGING  
LOCATION  
(Microlet Lancets):**

**HTL-STREFA S.A.  
ul. Adamówek 7  
95-035 Ozorkow  
POLAND**

**PLACE OF MANUFACTURE (Microlet Next Lancing  
Device):**

**HTL-STREFA S.A.  
Ul. Lotnicza 21h  
99-100 Leczyca  
POLAND**

**PACKAGING LOCATION (Microlet Next Lancing  
Device):**

**HTL-STREFA S.A.  
ul. Adamówek 7  
95-035 Ozorkow  
POLAND**

**RR Donnelley GTS Poland SP. z o.o.  
ul. Zakładowa 90/92  
92-402 Łódź  
Poland**

**PLACE OF MANUFACTURE (Microlet2 Lancing  
Device):**

**FACET Technologies, LLC  
101 Liberty Industrial Parkway  
McDonough, GA 30253  
USA**

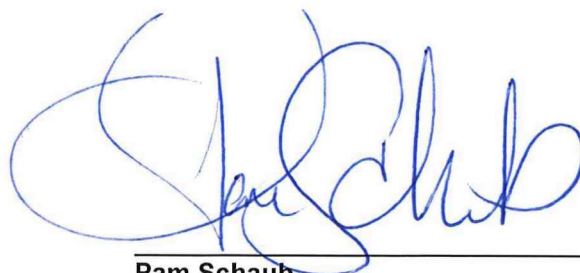
**Ascensia Diabetes Care US Inc.  
Diabetes Care  
430 S. Beiger Street  
Mishawaka, IN 46544  
USA**

**PACKAGING LOCATION (Microlet2 Lancing  
Device):**

**Ascensia Diabetes Care US Inc.  
Diabetes Care  
430 S. Beiger Street  
Mishawaka, IN 46544  
USA**

**RR Donnelley GTS Poland SP. z o.o.  
ul. Zakładowa 90/92  
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