

Declaration of Conformity

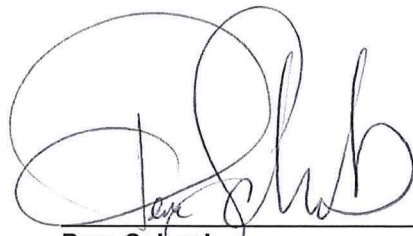
LEGAL MANUFACTURER:	Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel Switzerland
PLACE OF MANUFACTURE:	See page 2
PRODUCT CATEGORY:	System for Self-Testing of Blood Glucose
GMDN CODE:	Blood Glucose Meter: GMDN 62645 Blood Glucose Test Strips: GMDN 53302 Control Solution: GMDN 41819
PRODUCT:	Contour Next ONE blood glucose monitoring system, consisting of: Contour Next ONE Blood Glucose Meter Contour Next Blood Glucose Test Strips Contour Next Controls
CLASSIFICATION:	List B according to Annex II of directive 98/79/EC
CONFORMITY ASSESSMENT ROUTE:	Annex IV , excluding sections 4 and 6
NOTIFIED BODY:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Country : Netherlands Notified Body number : 2797
EC CERTIFICATE NUMBER:	CE 711083

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

- the Directive 98/79/EC Of The European Parliament And Of The Council on In Vitro Diagnostic medical devices
- the RED Directive (2014/53/EU) of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment <https://www.diabetes.ascensia.com/declarationofconformity/>
- the RoHS Directive (2011/65/EU) of the European Parliament of the Council of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment

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

2019-11-22
Basel, Switzerland



Pam Schaub
Head of Global Regulatory Affairs

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PLACE OF MANUFACTURE:

Contour Next ONE Blood Glucose Meters:

**PHC Corporation
In Vitro Diagnostics Division
Wakimachi Plant
110 Oaza-Inoshiri-aza-Nishiueno
Wakimachi, Mima
Tokushima 779-3603
Japan**

**PT PHC Indonesia
Kawasan Industri MM2100 Blok O-1
Cikarang Barat
Bekasi 17520
Indonesia**

Contour Next Blood Glucose Test Strips:

**PHC Corporation
In Vitro Diagnostics Division
2131-1 Minamigata
Toon, Ehime, 791-0395
Japan**

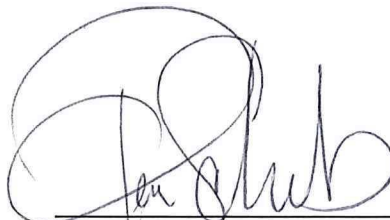
Contour Next Controls:

**Bionostics, Inc.
7 Jackson Road
Devens MA 01434
United States of America**

Packaging Location:

**RR Donnelley GTS Poland Sp. z o. o.
ul. Zakładowa 90/92
92-402 Lodz
Poland**

**2019-11-22
Basel, Switzerland**



**Pam Schaub
Head of Global Regulatory Affairs**