

Declaration of Conformity

LEGAL MANUFACTURER:	Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel Switzerland
EU AUTHORIZED REPRESENTATIVE:	Ascensia Diabetes Care Italy S.r.l. Via Varesina, 162 20156 Milano Italy
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 53307 Control Solution: GMDN 41819
PRODUCT:	Contour Next blood glucose monitoring system, consisting of: Contour Next Blood Glucose Meter (Connected 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 and RoHS 3 (EU 2015/863) 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.

2022-05-18
Basel, Switzerland



Pam Schaub
Head of Global Regulatory Affairs

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PLACE OF MANUFACTURE:

Contour Next (connected) Blood Glucose Meters

Manufacturing:

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

Contour Next Blood Glucose Test Strips Manufacturing:

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

Contour Next Controls Manufacturing:

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

Alternative packaging location (Strips):

RR Donnelley, Global Turnkey Solutions
1600 Disk Drive
Plover WI 54467
United States of America

Alternative packaging location (kits):

RR Donnelly Global Turnkey Solutions Mexico S.DE.R.L DE D.V.
Boulevard Internacional #881
San Jeronimo
Chihuahua, C.P. 32505
Mexico

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