

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 XT blood glucose monitoring system,

consisting of:

Contour XT 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 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

Pa

Pam Schaub Head of Global Regulatory Affairs



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PLACE OF MANUFACTURE:

Contour XT 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

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Pam Schaub

Head of Global Regulatory Affairs