Declaration of Conformity

LEGAL MANUFACTURER:	**Ascensia Diabetes Care Holdings AG** **Peter Merian-Strasse 90** **4052 Basel** **Switzerland**
PLACE OF MANUFACTURE:	**Kimball Electronics Poland sp. z o.o.** **ul. Poznanska 1C** **62-080 Tarnowo Podgorne** **Poland**
PRODUCT CATEGORY:	**Self-Testing of Urine Glucose & Ketone**
GMDN CODE:	**Diastix: GMDN 54518** **Ketostix: GMDN 54519** **Keto-Diastix: GMDN 54514**
PRODUCT(S):	**Urine test strips:** **Diastix Reagent Strip** **Ketostix Reagent Strip** **Keto-Diastix Reagent Strip**
CLASSIFICATION:	**Self-Testing according to Annex IV 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 herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for In vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

2019-11-22
Basel, Switzerland

Pam Schaub
Head of Global Regulatory Affairs