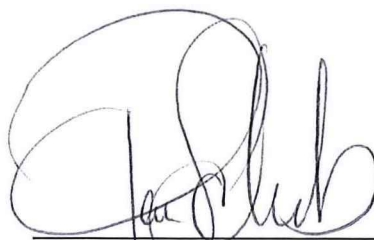


Declaration of Conformity

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