

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: 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

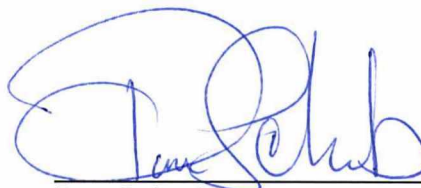
CONFORMITY ASSESSMENT ROUTE: Annex IV , excluding sections 4 and 6

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.

2022-05-18
Basel, Switzerland



Pam Schaub
Head of Global Regulatory Affairs