Declaration of Conformity Certificate

Manufacturer:	**SPD Swiss Precision Diagnostics GmbH** **47, Route de Saint-Georges** **1213 Petit-Lancy, Geneva** **SWITZERLAND**
Product:	**Clearblue Ultra Early Pregnancy Test (Clearblue Early Detection Pregnancy Test, Clearblue Pregnancy Test Early Detection) - (Variants listed in Appendix 1)**
Product Code:	**CB14**
Device Classification:	**Self – Test**
Conformity Assessment Procedure:	**Annex IV (excluding sections 4 and 6) of the Directive: 98/79/EC on In Vitro Diagnostic Medical Devices**
EC Certificate No:	**98/79/EC IVDD 099371 0009**
EC Certificate Expiry Date:	**2025-05-26**
Notified Body:	**TÜV SÜD Product Service GmbH, Ridlerstraße 65, D-80339 München, Germany. Notified Body Number: 0123**

We hereby declare that the above-mentioned product meets the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices as transposed into National Legislation.

This declaration is issued under the sole responsibility of the manufacturer stated above.

For and on behalf of
SPD Swiss Precision Diagnostics GmbH

Kim French

Position: Regulatory Director

Place of Issue: SPD Development Company Limited
Clearblue Innovation Centre, Stannard Way, Priory Business Park,
Bedford, MK44 3UP, UNITED KINGDOM

Date: 25 May 2022

Code: DC-0199 **Print Date:** 03-Jan-2023
Rev: 6 **Status:** Current
Effective Date: 25-Nov-2022
Document valid for use on date of printing.

Appendix 1 Variant Codes

Pouched Device Code	Description
CB14001	CB14 Visual Pouched Device-English
CB14002	CB14 Visual Pouched Device –Blank
CB14004	CB14 Visual Pouched Device-English FDOM
CB14005	CB14 Visual Pouched Device –Blank FDOM
CB14007	CB14 Visual Pouched Device – German

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Pre Design Freeze ☐	Post Design Freeze ☐	Non Project ☒

1 Summary

File note to accompany DC-0199 - Clearblue Ultra Early Pregnancy (Clearblue Early Detection Pregnancy test, Clearblue Pregnancy Test Early Detection) -CB14.

2 Detailed Information

2.1 Details of Change

To provide the statement that the EU Authorised Representative for the device named above with the European Union is:

Medical Device Safety Service GmbH (MDSS) has been appointed SPD's Authorised Representative for products placed on the market in EEA. Details for MDSS are:

Medical Device Safety Service GmbH at this moment)
Schiffgraben 41
Hannover 30175
Germany

2.2 Declaration

We hereby declare that DC-0199 - Clearblue Ultra Early Pregnancy (Clearblue Early Detection Pregnancy test, Clearblue Pregnancy Test Early Detection) -CB14 complies with all the provisions of the In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD). Accordingly, the CE mark with Notified Body registration number 0123 will be placed on all production batches placed on the market in the European Union and EEA member states as defined in Section 3 of this document. The manufacturer retains all supporting documentation. The declaration of conformity is issued under the sole responsibility of the manufacturer.

This is not a significant change according to MDCG-20022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR.

3 Approval

For and on behalf of SPD Swiss Precision Diagnostics GmbH

Name: KIM FRENCH

Signature: 

Position: REGULATORY DIRECTOR

Date: 24 NOV 2022

Code: DC-0199 **Print Date:** 03-Jan-2023
Rev: 6 **Status:** Current
Effective Date: 25-Nov-2022
Document valid for use on date of printing.

4 Revision History

Revision	Author	Reason for issue
03	Tosin Akisanya	Changes to make cover notes specific to DoC
02	Kate Sharman	Update to include the 'Declaration' section and definition of EEA.
01	Kate Sharman	New Release