

Manufacturer 	SPD Swiss Precision Diagnostics GmbH Route de Saint-Georges 47, 1213 Petit-Lancy, Geneva Switzerland
Single Registration Number (SRN)	CH-MF-000025175
Authorised Representative 	MDSS GmbH Schiffgraben 41 Hannover 30175 Germany
EC REP SRN	DE-AR-000005430
This declaration of conformity is issued under the sole responsibility of the manufacturer mentioned above.	
Basic UDI-DI	4084500DOTB5
Product Name	Clearblue Digital Ovulation Test
Product Code	DOT
Intended Purpose	This product consists of a reusable electronic holder and single-use test sticks. It is an automated, at home, self-testing device which semi-quantitatively detects the surge in luteinising hormone (LH) in a woman's urine to identify peak fertility (highest chance of conceiving). The LH surge precedes ovulation by 24-36 hours.
The above-mentioned device is in conformity with Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5 2017 on in vitro diagnostic medical devices.	
Risk Class	B
Conformity Assessment Procedure	Annex IX
EU Certificate No:	V74 099371 0018 Rev. 00
EU Certificate Expiry Date:	28/01/2030
Quality Management Certificate No:	V13 099371 0029 Rev. 00
Quality Management Certificate Expiry Date:	27/10/2030
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich Germany
Notified Body Number	0123
Common Specifications Applied	N/A
Additional Information	N/A

The above-mentioned device is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Harmonised Standards or Technical Specifications Applied	IEC 63000:2016 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Additional Information	It has been demonstrated that the requirements specified in 2011/65/EU Article 4 have been met.

Signed for and on behalf of SPD Swiss Precision Diagnostics GmbH



Kamila Przedmojska

Position: Regulatory Affairs Manager- International

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Place of Issue: SPD Bedford, UK.

Appendix 1 Variant Codes

Pouched Device Code	Description
UO0026	DOT with holder 81727396
UO0029	DOT with holder 80777418

Appendix 2 Translation into the Language of EEA Countries

Countries	Translation
Albania	Albanian
Austria	German
Belgium	French, Dutch, German
Bulgaria	Bulgarian
Croatia	Croatian
Czech Republic	Czech
Denmark	Danish
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Italy	Italian
Netherlands	Dutch
Norway	Norwegian
Portugal	Portuguese
Romania	Romanian
Serbia	Serbian
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
Switzerland	Swiss French, Swiss German, Swiss Italian

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Approved By:

[\(CO-6101\) Update of DoCs](#)

Description

Update of DoCs due to updated template, new languages added due to FPC-0001 update, changes in the position, Appendix 1 for COMBOS have been made uniform, IUS statement updated to match the certificate, updated the QMS Cert number and expiry date for some DoCs The translations to be uploaded as supporting documents after back translations have been done, as per G-WI-0219

Justification

Update of DoCs

Assigned To:

Shanice Njeri-Okusanya

Initiated By:

Shanice Njeri-Okusanya

Priority:

Low

Impact:

Minor

Version History:

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