LifeScan Europe GmbH
Gubelstrasse 34
6300 Zug, Switzerland
Tel. +41 (0) 58 231 50 50 Fax +41 (0) 58 231 50 51

Declaration of Conformity

In accordance with the IVD Directive 98/79/EC

1. Legal Manufacturer Details

LifeScan Europe GmbH, Gubelstrasse 34, 6300 Zug, Switzerland.

2. Authorized Representative

Not required – Legal Manufacturer based in Switzerland

3. Declaration

3.1 IVD Directive 98/79/EC

We hereby declare under our sole responsibility of manufacturer that the distributed CE Marked products specified in Section 4 below conform to the type covered by the EC Certificate issued to LifeScan Europe GmbH with certificate 2231396CE01 by DEKRA Certification B.V, Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex I Essential Requirements of the IVD Directive 98/79/EC of 27TH October 1998 concerning In Vitro Diagnostic Medical Devices.

Furthermore, we ensure and declare that the distributed CE marked products as mentioned and falling within Annex II List B met the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned in accordance with Annex IV of the EC-Directive as described in the said CE Marking of Conformity Certificate, issued by DEKRA Certification B.V.

This declaration is supported by the Quality System certification based on ISO 13485:2016 and the harmonized standard EN ISO 13485:2016. Quality System Certificate issued to LifeScan Europe GmbH with certificate number 2231533 by DEKRA Certification B.V, Arnhem, The Netherlands and applicable certification notice in accordance with their terms and conditions.

In addition to this, the products have been designed manufactured, verified and validated in accordance with the European Harmonized Standard, EN ISO 15197:2015 – In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO15197:2013)

Additional Directives.

Furthermore, we declare that the products listed in section 4 below meet the provisions and requirements of the following EC Council Directives:

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- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU as per Article 7
- Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/CE

4. Description of the devices

Blood glucose meter

Intended use: *In vitro* diagnostic blood glucose monitoring device

Brand: OneTouch®

Scope and Product Categories[1,2]	Added to DoC on	EU Market Exit Date[3]	GMDN Codes[4]
OneTouch® Verio®IQ Blood Glucose Monitoring System	8th October 2018	-	62537
OneTouch® Verio™ Blood Glucose Monitoring System (serial number prefixed with 'X') [Alternate trade name OneTouch® Verio®2 Blood Glucose Monitoring System]	8th October 2018	-	62537
OneTouch VerioVue™ Blood Glucose Monitoring System	8th October 2018	-	62537
OneTouch Select® Plus Blood Glucose Monitoring System	8th October 2018	-	62537
OneTouch Select Plus Simple Blood Glucose Monitoring System (including silent variant meter) and Variant Meter (with the buzzer component removed) (serial number contains Product Code 'B')	8th October 2018	-	62537

Notes

1. Legal manufacturer identification for these products on artwork is indicated by GS1 code **7613427xxxxxxP**
2. If national regulations require identification of specific part numbers these can be found in the Addendum attached to this Declaration of Conformity.
3. This is the date when a device is no longer placed on the EU Market
4. Each Blood Glucose Monitoring System (GMDN 62537; Home-use blood glucose monitoring system IVD) comprises some or all of the following components and their associated GMDN Codes:

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GMDN Code	Description
62645	Home-use glucose analyser IVD, battery-powered (Blood Glucose Meter)
53303	Glucose IVD, kit, electrometry (Blood Glucose Test Strip)
41819	Glucose IVD, control (Glucose Quality Controls)

NOTE: This declaration of conformity for the products listed above is only valid when the meters are used with the compatible Test Strips and Controls Solutions Listed below:

- OneTouch Verio, OneTouch VerioIQ, OneTouch VerioVue meters are compatible with OneTouch Verio Test Strips and OneTouch Verio Control Solutions.
- OneTouch Select Plus, OneTouch Select Plus Simple meters are compatible with the OneTouch SelectPlus Test Strips and OneTouch SelectPlus Control Solutions.

5. Declaration made on behalf of Legal Manufacturer by:

Date:	15 July 2021
Place:	Zug, Switzerland
Signature:	Ο.Π Περιστερά
Name:	Ourania Peristera
Position	Regulatory Affairs Manager

6. Revision History

Version	Author	Description of Change
1	Gordon McIvor	New DOC for LifeScan GmbH
2	Joanne Slater	Added Select Plus Simple 'silent' meter variant
3	Joanne Slater	Removed product revision for Select Plus Simple 'silent' meter variant
4	Joanne Slater	Added Select Plus Simple Meter Variant (with the buzzer component removed)
5	Joanne Slater	Added document title
6	Jenny Mackenzie	Adding European Authorized Representative
7	Joanne Slater	Removed Authorised Representative (as not required until May 2022)