LifeScan Europe,
Division of Cilag GmbH International
Gubelstrasse 34, CH-6300, Zug,
Switzerland

1. Legal Manufacturer Details

LifeScan Europe, a Division of Cilag International, 6300 Zug, Switzerland.

2. Authorized Representative

Not required – Legal Manufacturer based in Switzerland

3. Declarations

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 with certificate 2138338CE01. Issued for the first time on October 20, 2010 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. The products specified in Section 4 below are indicated for self-testing and professional use.

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 with certificate number 2173988. Issued on February 2018 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)

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3.2 Radio Equipment Directive 2014/53/EU

We hereby declare under our sole responsibility of manufacturer that the distributed CE Marked products, specified in Section 4 below, conform with the Essential Requirements and other relevant requirements of the Radio Equipment Directive (2014/53/EU). This declaration is based on the application of Conformity Assessment Module A, Annex II of the Directive 2014/53/EU.

The products conform with the following standards:

Health and Safety (Art. 3 (1)(a))	EN 62311:2008 EN 62479:2010 EN 62368-1:2014
EMC (Art. 3 (1)(b))	EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1
Spectrum (Art. 3 (2))	EN 300 328 V2.1.1
Other (Including Art. 3 (3))	N/A

3.3 Additional Directives

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

- 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 with Bluetooth® connectivity

Intended use: *In vitro* diagnostic blood glucose monitoring device. Self-testing and professional use.

Brand: OneTouch®

Scope and Product Categories[1,2]	Added to DoC on	EU Market Exit Date[3]	GMDN Codes[4]
OneTouch Verio Reflect Blood Glucose Monitoring System (Serial Number prefixed with 'K')	29th October 2018	-	62537 and 62538

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Scope and Product Categories[1,2]	Added to DoC on	EU Market Exit Date[3]	GMDN Codes[4]
OneTouch Ultra Plus Reflect Blood Glucose Monitoring System (Serial Number prefixed with 'P')	12th November 2018	-	62537 and 62538

Notes

1. Legal manufacturer identification for these products on artwork is indicated by GS1 code **4030841xxxxxxP**
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 and 62538; Self-testing and professional use blood glucose monitoring systems IVD comprises some or all of the following components and their associated GMDN Codes

GMDN Code	Description
62537	Home-use blood glucose monitoring system IVD, battery-powered (Blood Glucose Meter)
62538	Point-of-care blood glucose monitoring system IVD, battery-powered (Blood Glucose Meter)
53303	Glucose IVD, kit, electrometry (Blood Glucose Test Strip)
41819	Glucose IVD, control (Glucose Quality Controls)
62645	Home-use glucose analyser IVD, battery-powered (Blood Glucose Meter)

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 Reflect meters are compatible with OneTouch Verio Test Strips and OneTouch Verio Control Solutions
- OneTouch Ultra Plus Reflect meters are compatible with OneTouch Ultra Plus Test Strips and OneTouch Ultra Plus Control Solutions

Radio Frequency Specifications

Frequency band	2.4–2.4835 GHz
Maximum power	0.4 mW
Type of antenna	Custom PCB trace
Type of modulation	GFSK
Channel spacing	2 MHz
Bit rate	1000 kbps

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5. Declaration made on behalf of Legal Manufacturer by:

Date:	15/11/2018
Place:	Zug, Switzerland
Signature:	
Name:	Mariano Chiusano
Position	Regulatory Affairs Director, EMEA

6. Revision History

Version	Author	Description of Change
2	Gordon McIvor	Addition of Ultra Plus Reflect Blood Glucose Monitoring System
1	Gordon McIvor	New DOC for LifeScan Europe, a Division of Cilag International