EC CERTIFICATE

Number: 2231396CE01

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4,6)
(List A, B and devices for self-testing)

Manufacturer:

LifeScan Europe GmbH

Gubelstrasse 34
6300 Zug
Switzerland

For the product category(ies)

Blood Glucose Monitoring Systems

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2231396CN, initially dated 8 October 2018
Addendum, initially dated 8 October 2018

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex IV of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance. For placing on the market of List A devices an additional EC design examination certificate according to Annex IV (4) is mandatory.
The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 8 October 2018
Reissued: 15 August 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2231396CE01

CE MARKING OF CONFORMITY
IN VITRO DIAGNOSTIC MEDICAL DEVICES

Blood Glucose Monitoring Systems

Issued to:

LifeScan Europe GmbH
Gubelstrasse 34
6300 Zug
Switzerland

This certificate covers the following product(s):

Products:

OneTouch® Verio®IQ Blood Glucose Monitoring System

OneTouch® Verio™ Blood Glucose Monitoring System (serial number prefixed with 'X') brand names OneTouch® Verio and OneTouch® Verio®2

OneTouch® VerioVue Blood Glucose Monitoring System

OneTouch® Select® Plus Blood Glucose Monitoring System

OneTouch® Verio® Flex™ Blood Glucose Monitoring System

OneTouch® Select Plus Flex™ Blood Glucose Monitoring System

OneTouch® Ultra Plus Flex™ Blood Glucose Monitoring System

OneTouch® Select Plus Simple™ Blood Glucose Monitoring System

OneTouch® Verio Reflect™ Blood Glucose Monitoring System

OneTouch® Ultra Plus Reflect™ Blood Glucose Monitoring System

Initial date: 8 October 2018
Revision date: 6 November 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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