

# CERTIFICATE

Number: 2231533

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## LifeScan Europe GmbH

Gubelstrasse 34  
6300 Zug  
Switzerland

including the implementation meets the requirements of the standard:

# ISO 13485:2016 EN ISO 13485:2016

### Scope:

Design, manufacture and distribution of electro-chemical in-vitro diagnostic systems used in monitoring blood glucose including meters, test strips, control solutions, lancets, lancing devices and data management software, for health care professional use and home use.

Manufacture and distribution of in-vitro diagnostic systems used in monitoring ketones including meters, test strips, control solutions, linearity kit, and data management software for use by health care professionals.

Design, manufacture and distribution of stand-alone software for diabetes management for health care professional use and home use.

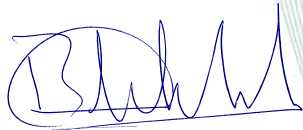
Certificate expiry date: 15 February 2024

Certificate effective date: 15 August 2021

Certified since: 8 October 2018

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



# ADDENDUM

To certificate: 2231533

The management system of the organization(s) and/or location(s) of:

## LifeScan Europe GmbH

Gubelstrasse 34  
6300 Zug  
Switzerland

Certified organization(s) and/or locations:

Lifescan Inc  
20 Valley Stream Pkwy  
19355 Malvern, PA  
United States Of America

Different scope

Design, manufacture and distribution of electro-chemical in-vitro diagnostic systems used in monitoring blood glucose including meters, test strips, control solutions, lancets, lancing devices and data management software, for health care professional use and home use.

Distribution of in-vitro diagnostic systems used in monitoring ketones including meters, test strips, control solutions, linearity kit, and data management software for use by health care professionals.

Design, manufacture and distribution of stand-alone software for diabetes management for health care professional use and home use.

LifeScan Scotland Ltd.  
Beechwood Park North  
IV2 3ED Inverness, Scotland  
United Kingdom

Design, manufacture and distribution of electro-chemical in-vitro diagnostic systems used in monitoring blood glucose including meters, test strips, control solutions, lancets, lancing devices and data management software, for health care professional use and home use.

Manufacture and distribution of in-vitro diagnostic systems used in monitoring ketones including meters, test strips, control solutions, linearity kit, and data management software for use by health care professionals.

Design, manufacture and distribution of stand-alone software for diabetes management for health care professional use and home use.

Addendum expiry date: 15 February 2024

Addendum effective date: 15 August 2021