DEKRA

LifeScan Europe GmbH
Dammstrasse 19
6300 Zug
Switzerland

Your ref.
Our ref. CA-25-084
Tel. +31 88 96 83009
Fax +31 88 96 83100
E-mail medical.nl@dekra.com

Arnhem, 10 April 2025

Subject: **Extension of validity of DEKRA Certification B.V. Certification Agreement for continuation of IVDD 98/79/EC surveillance activities, in reference to Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulation (EU) 2017/746 as regards the transitional provision for certain *in vitro* diagnostic medical devices.**

Dear Ms. R. Macleod,

Introduction:
Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulation (EU) 2017/746 as regards the transitional provision for certain *in vitro* diagnostic medical devices has been published on 9 July 2024 and came into force on the same day.

This Regulation (EU) 2024/1860 has amended Regulation (EU) 2017/746 (from here referred to as IVDR 2017/746) to now identify that under certain conditions certificates issued by notified bodies in accordance with Directive 98/79/EC that were still valid on 26 May 2022 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate under certain conditions. Additionally should the manufacturer intend to make use of the extension of the validity of the certificates, involvement of a notified body for continued surveillance is required.

This agreement identifies the devices and certificates for which the required conditions are met and that the manufacturer intends to make use of the options for extension of the validity of the certificates. The agreement also identifies the conditions under which DEKRA Certification B.V. will be the notified body responsible for continued surveillance. In order for DEKRA Certification B.V. to continue these surveillance activities the Certification Agreement in place with the manufacturer will be extended, as detailed further below.

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands
T +31 88 96 83 009 F +31 88 96 83 100 medical.nl@dekra.com www.dekra.nl
Registered Arnhem 09085396

Agreement:
LifeScan Europe GmbH has identified the intention to make use of the options for extension of the validity of the certificates as detailed in the amendment of the IVDR 207/746 by Regulation (EU) 2024/1860.

Evidence has been provided by LifeScan Europe GmbH that they meet the following condition(s) for the certificates issued by DEKRA Certification B.V. in accordance with Directive 98/79/EC to remain valid:

- LifeScan Europe GmbH holds certificates issued by DEKRA Certification B.V. in accordance with Directive 98/79/EC that were still valid on 26 May 2022 and that have not been withdrawn afterwards and were not expired on 9 July 2024 and:
    (a) Has already lodged a formal application with a notified body in accordance with IVDR 2017/746 Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of the device or in respect of the device intended to substitute that device.
    (b) A written agreement in accordance with IVDR 2017/746 Section 4.3, second subparagraph, of Annex VII, is already in place between the notified body to which the formal application has been made and LifeScan Europe GmbH.

Based on evidence provided by LifeScan Europe GmbH it has been determined that the following Directive 98/79/EC DEKRA Certification B.V. certificates of LifeScan Europe GmbH for the devices indicated below meet the requirements to remain valid:

Certificate number	Scope and product categories	Annex	Class & rule	Expiry date
2231396CE01	**Blood Glucose Monitoring Systems** **Products:** 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	IVDD, Annex IV	Annex II List B	26 May 2025

Certificate number	Scope and product categories	Annex	Class & rule	Expiry date
	OneTouch® Verio Reflect™ Blood Glucose Monitoring System OneTouch® Ultra *Plus* Reflect™ Blood Glucose Monitoring System			

It should be noted that the following devices still listed on the above certificates do not meet the requirements to continue to be placed on the market, and for these specific devices the certificate shall not continue to be considered valid:

Certificate Number	Devices
2231396CE01	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

By signing this agreement LifeScan Europe GmbH also confirms that the following additional requirements of IVDR 2017/746 Article 110 3c, as amended by Regulation (EU) 2024/1860, are met, and will continue to be met, for all products listed above which will continue to be placed on the market:

- those devices continue to comply with Directive 98/79/EC, as applicable;
- there are no significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

Following from the above information from LifeScan Europe GmbH DEKRA Certification B.V. agrees to be the notified body responsible for the continued appropriate surveillance in accordance with applicable requirements, and in the respect of the applicable devices identified above, as stipulated in IVDR 2017/746 Article 110 3e, as amended by Regulation (EU) 2024/1860, DEKRA Certification B.V. This appropriate surveillance shall include at least:

- Surveillance audits in accordance with Directive 98/79/EC, considering also IVDR 2017/746 requirements for post market surveillance, vigilance, registration of economic operators and of devices as required by IVDR 2017/746 Article 110. This can also include unannounced audits.
- Assessment of reportable changes
- Assessment of reportable adverse events (vigilance) for impact on certification status

For the specific devices given above for which the certificate(s) can still be considered valid, the certificate validity date and date until when the products may be placed on the market or put into service is **31 December 2027**.

DEKRA Certification B.V. is responsible for the appropriate surveillance until **31 December 2027**, unless one of the following situations applies:

- LifeScan Europe GmbH provides a Notification of Change to inform DEKRA Certification B.V. that devices will no longer be placed on the market or put into service and the certificate should no longer be considered to be valid
- DEKRA Certification B.V. is not the notified body with which the written agreement has been signed for conformity assessment of the device or substitute device in accordance with IVDR 2017/746. In this case the notified body with which the written agreement has been signed for conformity assessment of the device or substitute device must take responsibility for surveillance of the device which has a certificate that was issued in accordance with Directive 98/79/EC. This should be no later than 26 September 2025 as detailed in IVDR 2017/746 Article 110 3e, as amended by Regulation (EU) 2024/1860. Thus DEKRA Certification B.V.'s responsibility for surveillance will end on 26 September 2025 in this case, or before if a Notification of Change is provided to confirm that the surveillance activities are now carried out by another Notified Body.

Finally, by signing this agreement DEKRA Certification B.V. and LifeScan Europe GmbH agree that current Certification Agreement CA-25-084 which covers the products under the Directive 98/79/EC certificates listed above will thus continue to remain valid until the dates as stipulated above, in order for DEKRA Certification B.V. to meet the required surveillance responsibilities. This also includes that the manufacturer will continue to meet the following responsibilities as stipulated in that Certification Agreement:

- Allowing DEKRA to carry out appropriate surveillance activities in respect of the applicable requirements
- Reporting of significant changes to DEKRA Certification B.V. for assessment
- Reporting of adverse events (vigilance) to DEKRA Certification B.V. for assessment

Should you agree with the above please confirm this through a signature below.

Thus duly agreed, drafted and signed:

LifeScan Europe GmbH		DEKRA Certification B.V.	
Inverness, UK.	(place)	Arnhem	(place)
13 May 2025.	(date)	10 April 2025	(date)
P. Middleton	(signature)		(signature)
Paul Middleton.	(name)	B.T.M. Holtus	(name)
Head of Regulatory & Quality.	(title)	Managing Director	(title)