EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60149414 0001

Report No.: 21267490 006

Manufacturer:
Brighter AB (publ)
Borgarfjordsgatan 18
SE-164 40 Kista
Sweden

Products:
Portable diabetes self-management system for injection of insulin and for the measurement of blood sugar (combination device related to Directive 93/42/EEC)

(see attachement for product(s) included)
Replaces Certificate, Registration No.: HL 60140945 0001

Expiry Date: 2024-06-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2020-07-07

Date: 2020-07-07

Notified Body

Dipl.-Ing. U. Frenkert

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60149414 0001
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Products included:

- ACTISTE
- ACTISTE Mini

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Certifizierungsstelle

Date: 2020-07-07

Dipl.-Ing. U. Frenkert