EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149413 0001

Report No.: 21267490 008

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 98/79/EC)

(see attachement for product(s) included)
Replaces Certificate, Registration No.: HD 60140946 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 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 93/42/EEC concerning 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.: HD 60149413 0001
Report No.: 21267490 008

Manufacturer: Brighter AB (publ)
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Sweden

Products included:

- ACTISTE
- ACTISTE Mini

Date: 2020-07-07

Notified Body

Dipl.-Ing. U. Frenkert

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle