

Declaration of Conformity

The Manufacturer of the Product(s) Covered by this Declaration is:

Company Breas Medical AB
Address: Företagsvägen 1
SE-43533 Mölnlycke
Sweden
Telephone: +46 31 86 88 00
SRN: N/A

The Manufacturer hereby declares under the Manufacturer's sole responsibility that the product(s) identified below is in conformity with the DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), and DIRECTIVE 2014/53/EU (Radio Equipment Directive; RED) relating to the making available on the market of radio equipment.

The basis on which conformity is being declared:

RED: Annex II

Product(s) Covered by this Declaration:

Product	Art.no	Intended purpose	Radio equipment (Y/N) (RED)
iLink	007950	The iLink modem hardware is an Internet of Things (IoT) device with cellular connectivity to upload data from Breas devices to the cloud securely.	Y

Notified Body:

N/A

Product not subject to assessment by Notified Body

Mark of compliance:



Applied standards (RED and RoHS):

- EN IEC 62368-1:2020 + A11:2020
- EN 50385:2017
- ETSI EN 301 489-1 V2.2.3 (2019-11)
- ETSI EN 301 489-52 V1.1.0 (2016-11)
- ETSI EN 301 511 V12.5.1 (2017-03)
- ETSI EN 301 908-1 V13.1.1 (2019-11)
- ETSI EN 301 908-13 V11.1.2 (2017-07)
- EN 50581:2012

Signed

Name:

Sebastian Mommers

Title:

Managing Director Sweden
Breas Medical

Valid from

Date:

2020-08-31