

EC DECLARATION OF CONFORMITY FOR GETINGE CONNECT MODULE

Name and Address of the Manufacturer: Maquet Critical Care AB
Röntgenvägen 2
SE-171 54 Solna, Sweden

On our sole responsibility, we hereby declare that the product(s)

Product Description: Medical* Radio Equipment

Product Identification: “Getinge Connect module”
(See Annex 1)

Product-No.: See Annex I of this document

Classification (RED, R&TTED and Commission Decision 2000/299/EC): Class 1, subclasses 9a and 22.

Conformity Assessment Procedure (RED Article 17): Module A
(Internal production control)

*Getinge Connect module is not a *Medical device* according to MDD nor MDR –EC directives and regulations; although applicable parts of IEC60601-1 -standard series have been applied in order to comply to the environmental criteria’s where it is to be used in and essential requirements of RED (LVD and EMCD Incl.).

-comply with the relevant provisions and essential requirements of the following directive(s) and/or regulation(s):

Directive / Regulation.	Standard(s).	Certificate ID.
Directive 2014/53/EU on Radio equipment. Health & Safety (Article 3.1a) (with essential req. of Low Voltage Directive, LVD)	IEC 60601-1:2005 COR1:2006, COR2: 2007 AMD1:2012 (or IEC 60601-1:2012 reprint)	1916963STO-001
Directive 2014/53/EU on Radio equipment. Electromagnetic compatibility, EMC (Article 3.1b) (with essential req. of Electromagnetic Compatibility Directive, EMCD)	IEC 60601-1-2:2014 EN 301489-1 V2.1.1, EN 301489-17 V3.1.1, EN 301489-52 V.1.1.0_Draft (2016)	1916145STO-001 1916145STO-002

Directive / Regulation.	Standard(s).	Certificate ID.
Directive 2014/53/EU on Radio equipment. Radio Spectrum Efficiency (Article 3.2)	ETSI EN 300328 V2.1.1 ETSI EN 301893 V2.1.1 ETSI EN 301 908-1 V11.1.1	1916146STO-001
Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment (RoHs 2). Prevention (Article 4.1)	EN 50581:2012 EN ISO 13485:2016	ISO13485 certificate Certificate No. Q5 072017 0013 (upon request)

This declaration is valid until the next change of the product. Any modification of the product not authorized by us will invalidate this declaration.

For the signature of the Manager for Product Compliance on behalf of Maquet Critical Care AB see left corner of page.

For the corresponding information in regards to **pre-certified radio modules** from manufacturer **U-blox** -please see the following document(s):

EU Declaration of Conformity for EMMY-W1 Host-based multiradio module:

“EMMY-W1_Conformity_(UBX-16007139).pdf”
https://www.u-blox.com/sites/default/files/EMMY-W1_Conformity_%28UBX-16007139%29.pdf

EU Declaration of Conformity for LARA-R211 Multi-mode LTE module:

”LARA-R211_DoC_(UBX-18049943).pdf”
https://www.u-blox.com/sites/default/files/LARA-R211_DoC_%28UBX-18049943%29.pdf

For the corresponding information in regards to **pre-certified battery** from manufacturer **VARTA Microbattery GmbH** -please see the following documents:

Type No.: CR2032
 Article No.: 6032 401 501

“MSDS_05_Primary_Lithium_Button_Series_CR_en.pdf”
https://products.varta-microbattery.com/applications/mb_data/documents/material_safety_data_sheets/MSDS_05_Primary_Lithium_Button_Series_CR_en.pdf

“DS6032.pdf”
https://products.varta-microbattery.com/applications/mb_data/documents/data_sheets/DS6032.pdf

For the corresponding information in regards to **pre-certified Power supply unit** from manufacturer **GlobTek Inc.** -please see the following documents:

EU Declaration of Conformity for GTM91120-30VV-T2 Wall Plug-in+Desktop Combination Medical/ITE/Household use Power Supply:
https://globtek.secure.force.com/models/ec_declaration?id=a0Oa000000C2VkdEAF&m=1

<https://en.globtek.com/model/medical-ite-household-use-power-supply/wall-plug-in-desktop-combination/gtm91120-30vv-t2/a0Oa000000C2VkdEAF>

ANNEX I TO THE EC DECLARATION OF CONFORMITY FOR GETINGE CONNECT MODULE

Product(s) Covered:

Trade Name	Article No.
Getinge Connect module X10 (Wi-Fi only)	6889600
Getinge Connect module X20-EU (Wi-Fi and LTE)	6889300

EUV-211502 - EC Declaration of Conformity DoC (RED) Getinge Connect module Version: 02 Approved at 2021-06-11 by: Jerker Åberg u2773956