Sensium

Declaration of Conformity

Sensium Healthcare Ltd
115 Olympic Avenue, Milton Park, Abingdon, OX14 4SA, UK

European Authorized Representative: - The Surgical Company International B.V. Beeldschermweg 6F, (3821 AH) Amersfoort, The Netherlands

Sensium Healthcare Ltd declare under our sole responsibility that

Product: **SensiumVitals Home Bridge**
Model Number **SH20222x**

as part of the TZ202001 Sensium System, is in conformity with the relevant Union harmonisation legislation:

Directive 2014/53/EU	on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment
Directive 2011/65/EU	on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive 2012/19/EU	on waste electrical and electronic equipment (WEEE)

ETSI EN 300 220-2 V3.1.1 (2017-02)
ETSI EN 301 511 V12.5.1
ETSI EN 301 908-13 V13.1.1
ETSI EN 301 489-1 V2.2.0 (2017-03)
ETSI EN 301 489-3 V2.1.1 (2017-03)
ETSI EN 301 489-52 V1.1.0 (2016-11)
EN 60601-1-2:2015 + A1:2014
EN 60601-1:2006+A1:2013+A12:2014
EN 60601-1-11:2015 + A1:2021
EN IEC 62311:2020
EN IEC 63000:2018
EN 50419:2006

Signature	
Name	Bruce Slaymaker
Position	Regulatory and QA Manager
Date	31st-July-2021