

Sensium

Declaration of Conformity

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

Sensium Healthcare Ltd declare under our sole responsibility that

Product: SensiumVitals Patch
Model Number SH202166

as part of the SH202001 Sensium System, is in conformity with the relevant UK legislation:

S.I. 2017/1206 Radio Equipment Regulations 2017

S.I. 2012/3032 Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

ETSI EN 300 220-2 V3.1.1 (2017-02)

ETSI EN 301 489-1 V2.2.0 (2017-03)

ETSI EN 301 489-3 V2.1.1 (2017-03)

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

Signature



Name Bruce Slaymaker

Position Regulatory and QA Manager

Date 31-July-2021