

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 Patch
Model Number SH202166

as part of the SH202001 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

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