

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 TZ202056

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

ETSI EN 300 220-1 V3.1.1 (2017-02)

ETSI EN 300 220-2 V3.2.1 (2018-06)

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

EN 60601-1:2006+A1:2013+A12:2014

EN 62479:2010

Signature



Name Bruce Slaymaker

Position Regulatory and QA Manager

Date 20th December 2018