

EC Declaration of Conformity

We hereby declare under our sole responsibility
that the generic product group

Reusable SMARTsat SpO₂ Sensors

**Sensors for continuous and spot check measurement of functional arterial
oxygen saturation (SPO₂) and pulse rate**

REF No.	Type	Product
6020132002	SF7500	SoftFlap SpO ₂ sensor
6020132004	SC7500	SoftCap SpO ₂ sensor - Large
6020132006	W7500	SoftWrap SpO ₂ sensor
6020132010	SCM7500	SoftCap SpO ₂ sensor - Medium
6020132012	SF7500VM	SoftFlap SpO ₂ sensor
6020132014	SC7500VM	SoftCap SpO ₂ sensor - Large
6020132016	W7500VM	SoftWrap SpO ₂ sensor
6020132020	SC7500-L	SoftCap SpO ₂ sensor - Large, 1.8m cable
6020132021	SC7500-XL	SoftCap SpO ₂ sensor - Large, 2.5m cable
6020132025	SCM7500VM	SoftCap SpO ₂ sensor - Medium
6020132030	SC7500-LVM	SoftCap SpO ₂ sensor - Large, 1.8m cable
6020132254	EP7500	Ear Probe SpO ₂ sensor
6020132264	EP7500VM	Ear Probe SpO ₂ sensor
6020132300	SCP7500	SoftCap SpO ₂ sensor - Small
6020132305	SCP7500VM	SoftCap SpO ₂ sensor - Small

Conforms with the essential requirements of Annex I and Annex II of the Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices.

In accordance with Annex IX of the Council Directive 93/42/EEC the product has been classified as Class IIb.

Application of the CE-marking:



MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg

Validity:

Date of expiry: 31 December 2019

Issuer:

bluepoint medical GmbH & Co. KG
An der Trave 15
23923 Selmsdorf
Germany

Place, Date:

Selmsdorf, 02 July 2018

Legally binding signature:


Bernd Lindner
General Manager