

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	Type	Product
6020132014	0014752	SC7500VM, SoftCap SpO ₂ sensor - Large
6020132025	0014754	SCM7500VM, SoftCap SpO ₂ sensor - Medium
6020132305	0014753	SCP7500VM, SoftCap SpO ₂ sensor - Small
6020132030	0014760	SC7500-LVM, SoftCap SpO ₂ sensor - Large, 1.8m cable
6020132012	0014651	SF7500VM, SoftFlap SpO ₂ sensor
6020132016	0014851	W7500VM, SoftWrap SpO ₂ sensor
6020132264	0014850	EP7500VM, Ear Probe SpO ₂ sensor

Complies 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 as well as the requirements of Regulation (EU) 2017/745, Article 120, Chapter (3).

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: 02 November 2023

Issuer:

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

Place, Date:

Selmsdorf, 25 May 2021

Legally binding signature:

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Bernd Lindner
General Manager