EC Declaration of Conformity

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

Disposable SMARTsat SpO_2 Sensors

Sensors for continuous and spot check measurement of functional arterial oxygen saturation (SpO_2) and pulse rate

REF	Type	Product
6020131204	0015010	10-AP-VM, Adult Plaster Disposable SpO_2 Sensor
6020131207	0015011	10-PP-VM, Paediatric Plaster Disposable SpO_2 Sensor
6020131209	0015012	10-IP-VM, Infant Plaster Disposable SpO_2 Sensor
6020131211	0015013	10-NP-VM, Neonatal Plaster Disposable 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:

CE 0482

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: .....

Bernd Lindner
General Manager