EC Declaration of Conformity

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

Reusable SMARTsat SpO_2 Sensors

Sensors for continuous and spot check measurement of functional arterial oxygen saturation (SPO_2) 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
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:

CE 0482

DNV MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany

Validity: **Date of expiry: 31 December 2028**

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

Place, Date: Selmsdorf, 02 November 2023

Legally binding signature: .....

Bernd Lindner
General Manager