EC Declaration of Conformity

We hereby declare under our sole responsibility that the product

VM-2160 with accessories

Handheld Pulse Oximeter for continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate (PR)

REF	Type	Product
12020112001E	SMARTsat® Technology	VM2160 - 0012165 complete device - Central Europe
12020112001N	SMARTsat® Technology	VM2160 - 0012166 complete device - Scandinavia
12020112001S	SMARTsat® Technology	VM2160 - 0012167 complete device - Special Europe

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