EC Declaration of Conformity

We hereby declare under our sole responsibility
that the products

FLEXMAX (for Professional Use)
FLEXMAX-P (for Professional Use)
FLEXMAX-HC (for Home Use)
FLEXMAX-P-HC (for Home Use)

Sensors for continuous and spot check measurement of functional arterial oxygen saturation (SpO2) and pulse rate

Comply 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 products have been classified as Class IIb.

Application of the CE-marking:

CE 0482 MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg

Validity:	**Date of expiry: 31 October 2023**
Issuer:	bluepoint medical GmbH & Co. KG An der Trave 15 23923 Selmsdorf Germany
Place, Date:	Selmsdorf, 08 December 2020
Legally binding signature:	..... Bernd Lindner General Manager