

## DECLARATION OF CONFORMITY

Manufacturer	Hoffrichter GmbH Mettenheimer Straße 12-14 19061 Schwerin GERMANY
Medical Device Type	Ventilator
Medical Device Name <i>(Name of Medical Device or Medical Device Family)</i>	CARAT II pro
Type Number(s)	9LV203
Classification <i>(according Annex IX of Directive 93/42/EEC considering the Directive 2007/47/EC)</i>	IIb
Conformity Assessment Procedure	Annex II (without 4)
Notified Body <i>(only if NB involved in conformity assessment procedure)</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München GERMANY
NB Identification Number <i>(only if NB involved in conformity assessment procedure)</i>	0123

We, Hoffrichter GmbH, herewith declare under our sole responsibility that the aforementioned medical device meets all the provisions of the Directive 93/42/EEC considering the Directive 2007/47/EC which apply to it.

We further declare that the aforementioned medical device meets all the provisions of Directive 2011/65/EU (RoHS) which apply to it.

This Declaration of Conformity is valid until 31.10.2023 and is furthermore limited by the issuing of a revised declaration of conformity after any change of the product and/or by the expiration date of the certificate(s) issued by the notified body.

Schwerin, 05.11.2018

  
Dr. Michael Gregor, General Manager

Place, Date

Name, Function

