

XO CARE A/S	Document ID:	XOCARE-1383376708-63385
Declaration of Conformity	Date:	2020-10-29
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DECLARATION OF CONFORMITY

In accordance with Annex II MDD 93/42/EEC concerning medical devices

Manufacturer:	XO CARE A/S Håndværkersvinget 6 DK – 2970 Hørsholm Denmark	
Notified Body:	DNV GL Presafe AS Veritasveien 3 NO – 1363 Høvik Norway Notified Body ID-number: 2460	
Conformity assessment procedure:	Annex II of Medical Device Directive 93/42/EEC, Machine Directive 2006/42/EC RoHS Directive 2011/65/EU, WEEE Directive 2012/19/EU Authorization and Restriction of Chemicals REACH 1907/2006, Electrical equipment designed for use within certain voltage limits 2006/95/EC, Electromagnetic compatibility (Directive 2014/30/EC)	
Products:	Product name & description	Risk class
	XO FLEX XO FLEX is combined dental unit and patient chair which is to be used by dentists and other qualified personal for prevention and treatment of human teeth diseases	Ila

We, the manufacturer, hereby declare that the product identified above follows relevant requirements of the listed directives.

Hørsholm, 2020-10-29



Morten Flintrup, Chief Quality Manager

