EC 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	
EUDAMED SRN:	DK-MF-000003605	
Notified Body:	DNV Product Assurance AS Veritasveien 3 NO – 1363 Høvik Norway Notified Body number: 2460	
Conformity assessment procedure:	Annex II of Medical Device Directive 93/42/EEC (MDD)	
Products:	**Product name & description**	**Risk class**
	XO ODONTOSURGE **Basic UDI-DI:** B-XOOSUBL XO ODONTOSURGE is a high frequency electrosurgery device intended for use in cutting (removing) soft tissues and in controlling bleeding during surgical procedures including procedures in all disciplines of dentistry	IIb According to MDD Rule 9

We, the manufacturer, XO CARE A/S, is exclusively responsible for the declaration of conformity, and hereby declare that the product identified above is in compliance with relevant requirements of the European Medical Device Directive 93/42/EEC.

Hørsholm, 2023-01-23

Morten Flintrup
VP Quality and Regulatory Affairs