

DECLARATION OF CONFORMITY

Manufacturers Name:	Nouvag AG
Manufacturers Address:	St. Gallerstrasse 25, 9403 Goldach, Switzerland
CHRN (Swiss Single Registration Number):	CHRN-MF-20000098
EUDAMED SRN	CH-MF-000018882
EC REP Name and SRN:	NOUVAG Dental-und Medizintechnik GmbH, DE-AR-000005643
EC REP Address:	Schulthaißstraße 15, 78462 Konstanz, Germany
Nomenclature:	BUDI-DI: ++ENOU100031LG EMDN: Z12019080 UMDNS: 17-830
Name of the Device group:	Foot Pedals
Device(s) REF and Description:	See Annex
Classification:	Class I
Conformity assessment:	EC conformity declaration according to ANNEX II and ANNEX III, Regulation MDR 2017/745
Common Specifications	Not Applicable

This declaration of conformity is issued under the sole responsibility of Nouvag AG. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, the Regulation (EC) No 1907/2006 (REACH), Directive 2008/98/EC (Waste Framework Directive), Directive 2011/65/EU (RoHS2), and Directive 2012/19/EU (WEEE)

All supporting documentation is retained at the premises of the manufacturer.

Place and date of issue:

Goldach, 31.01.2022

Signature:



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Christian Micheletti
PRRC



Annex: list of devices

REF	Description
1501nou 1501ang	Foot pedal Vario IPX8 for DP30
1507nou 1507bow	Foot pedal Vario IPX8 for TCM 3000 BL / TCM 3000 BL Morcellator
1510nou	Foot pedal Vario IPX8 for MD30 / HighSurg 30
1511nou	Foot pedal Vario IPX8 for LipoSurg / DP30 LipoPlus
1513nou	Foot pedal On/Off IPX8 for DP30
1527nou	Foot pedal On/Off IPX8 for DP30 LipoPlus
1866nou	Foot pedal Vario IPX8 for MD11 / HighSurg 11
4242	Foot pedal air, vacuum regulator for Vacuson 40
15012	Foot pedal air, On/Off for Vacuson 18/40/60