

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: ++ENOU100032LJ EMDN: Z121101 UMDNS: 17-972
Name of the Device group:	Cooling tubes and clips
Device(s) REF and Description:	See Annex
Classification:	Class I (Rule 1)
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) and Directive 2008/98/EC (Waste Framework Directive).

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
1703	Irrigation nozzle for handpiece 1710nou
1705	Intra cooling pipe type 1 complete for contra angle
1712	Internal irrigation needle for contra angle
1733	Cooling tube clip for ORL Handpiece 1904/1907
1734	Cooling tube clip for ORL Handpiece 1905/1908
1735	Cooling tube clip for ORL Handpiece 1903/1906
1773	Silicone tubing 1x1x160mm for Y-connector
1777	Y-Splitter for internal and external cooling
1873	Clip-set, pgk 10 pcs, sterilizable
1881	Clip-set complete for contra angle, sterilizable
1956	Irrigation nozzle for handpieces 1903nou/1906nou/1950nou/1960nou
1964	Irrigation nozzle for ENT handpiece 1951nou/1961nou
1966	Irrigation nozzle for handpieces 1952nou/1962nou
5047	Irrigation tube for surgery-compass/oscillating saw
5072	Irrigation tube for surgery-sagittal saw
39149	Clip with internal/external irrigation needle for contra angle
39150	Internal irrigation needle for contra angle
39152	Y-Splitter with tubing for contra angle
39116	Internal irrigation needle for contra angle
39117	Clip for internal irrigation needle for contra angle