FSN Ref: WW20_C11607

FSCA Ref: C11607

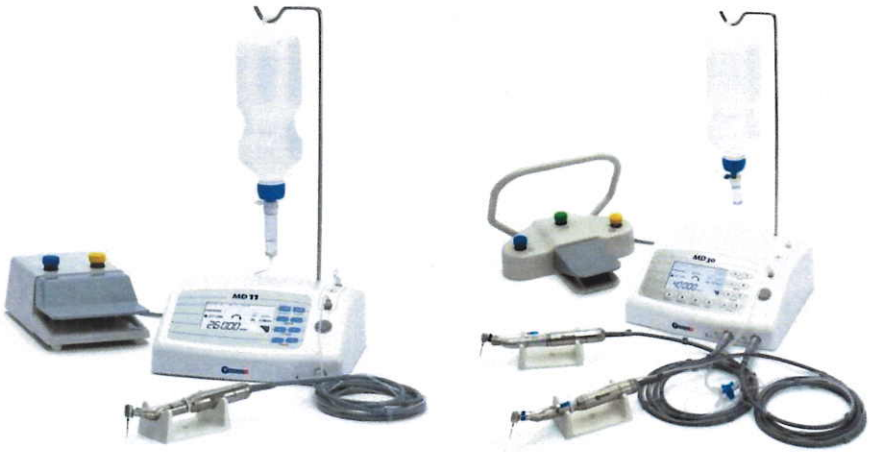
Date: 11.08.2020

Urgent Field Safety Notice MD11 / MD30

For Attention of: Quintess Denta, Irland

Contact details of local representative
Nouvag AG **Mehdi Zadehnour** **St. Gallerstrasse 23-25** **9403 Goldach** **+41 71 846 66 57**

Urgent Field Safety Notice (FSN) MD11 / MD30
Production according to expired EMV Standard 60601-1-2 Edition 3

	1. **Information on Affected Devices**
1.	1. Device Type
	The MD11 and MD30 is a mobile motor system with an integrated infiltration pump for oral surgery and implantology 
1.	2. Commercial name(s)
	Motor System MD11 Motor System MD30
1.	3. Unique Device Identifier(s) (UDI-DI)
	MD11 control unit: +ENOU33350H MD11 sets: +ENOU200308 +ENOU20260D +ENOU20270E +ENOU20280F MD30 control unit: +ENOU33300C MD30 sets: +ENOU200409 +ENOU20050A +ENOU20070C +ENOU20160C
1.	4. Primary clinical purpose of device(s)*

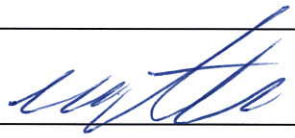
	The MD 30 in combination with a motor and corresponding handpiece or contra angle (separate medical device) is used primarily in dental implantology. The device can also be used for microsurgical applications as well as in oral and maxillofacial surgical procedures. The device is designed for drilling, milling and sawing bone as well as for screw insertion into bone. An integrated peristaltic pump is provided in order to cool the rotating instruments so that damage to tissue can be prevented.
1.	5. Device Model/Catalogue/part number(s)
	MD11 control unit and sets: 3335; 2003; 2026; 2027; 2027m; 2028 MD30 control unit and sets: 3330; 2004; 2005;
1.	6. Affected serial or lot number range

Qty	SET SN	UNIT SN
1	9804E1901R	4632U1810R
1	9805E1901R	4633U1810R
1	9806E1901R	4634U1810R
1	9813E1901R	4635U1810R
1	5936S1911R	9469U1907R

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	The devices MD 11 and MD 30 do not comply with the latest harmonized EMC standard (60601-1-2, Edition 4). The devices only comply with the expired Edition 3 and were not adapted to the new standard.
2.	2. Hazard giving rise to the FSCA
	The device might interfere with other electrical devices. The MD11 and MD30 could disturb the function of devices nearby or could itself be disturbed by them.
2.	3. Probability of problem arising
	Little to no probability of problems arising. The device still complies with the previous Edition 3 EMC standard (IEC 60601-1-2:2007). With the harmonization of the EMC standard Edition 4 (IEC 60601-1-2:2014) the acceptable ranges of electromagnetic interference is now smaller and thus not successfully achieved by the device.
2.	4. Predicted risk to patient/users
	none

	3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None		
	Device must be returned to the following address: Nouvag GmbH Dental und Medizintechnik Schulthaissstrasse 15 DE - 78462 Konstanz Germany Tel. +49 (0)7531 1290-0 Fax +49 (0)7531 1290-12 info-de@nouvag.com		
3.	2. By when should the action be completed?	Immediately	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes, As soon as possible

3.	4. Action Being Taken by the Manufacturer
	☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Device modification on manufacturing site

	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Nouvag AG**
	b. Address	**St. Gallerstrasse 23-25, CH-9403 Goldach**
	c. Website address	**www.nouvag.com**
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	6. Name/Signature	Mehdi Zadehnour, COO 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Please fill in the customer/ distributor reply form and send it to us before the defined deadline at: vigilance@nouvag.com