

Date: 11.08.2020


Urgent Field Safety Notice MD11 / MD30

For Attention of: Nouvag GmbH, Germany

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

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																																																																
	<table> <tr> <th>Qty</th><th>SET SN</th><th>UNIT SN</th></tr> <tr><td>1</td><td>8487E1901R</td><td>2959U1809R</td></tr> <tr><td>1</td><td>8488E1901R</td><td>2979U1809R</td></tr> <tr><td>1</td><td>9681E1901R</td><td>4628U1810R</td></tr> <tr><td>1</td><td>9682E1901R</td><td>4629U1810R</td></tr> <tr><td>1</td><td>9683E1901R</td><td>4672U1810R</td></tr> <tr><td>1</td><td>9684E1901R</td><td>4677U1810R</td></tr> <tr><td>1</td><td>6347E1905R</td><td>8399U1901R</td></tr> <tr><td>1</td><td>6348E1905R</td><td>8400U1901R</td></tr> <tr><td>1</td><td>6349E1905R</td><td>8401U1901R</td></tr> <tr><td>1</td><td>6625E1905R</td><td>8403U1901R</td></tr> <tr><td>1</td><td>6626E1905R</td><td>8404U1901R</td></tr> <tr><td>1</td><td>0358S1907R</td><td>0632U1902</td></tr> <tr><td>1</td><td>0359S1907R</td><td>0633U1902R</td></tr> <tr><td>1</td><td>3563S1909R</td><td>5455U1904R</td></tr> <tr><td>1</td><td>5404S1911R</td><td>9464U1907R</td></tr> <tr><td>1</td><td>5988S1911R</td><td>9470U1907R</td></tr> <tr><td>1</td><td>6651S1911R</td><td>5432U1904R</td></tr> <tr><td>1</td><td>6652S1911R</td><td>5433U1904R</td></tr> <tr><td>1</td><td>7065S1912R</td><td>2911U1909R</td></tr> <tr><td>1</td><td>7066S1912R</td><td>2912U1909R</td></tr> </table>		Qty	SET SN	UNIT SN	1	8487E1901R	2959U1809R	1	8488E1901R	2979U1809R	1	9681E1901R	4628U1810R	1	9682E1901R	4629U1810R	1	9683E1901R	4672U1810R	1	9684E1901R	4677U1810R	1	6347E1905R	8399U1901R	1	6348E1905R	8400U1901R	1	6349E1905R	8401U1901R	1	6625E1905R	8403U1901R	1	6626E1905R	8404U1901R	1	0358S1907R	0632U1902	1	0359S1907R	0633U1902R	1	3563S1909R	5455U1904R	1	5404S1911R	9464U1907R	1	5988S1911R	9470U1907R	1	6651S1911R	5432U1904R	1	6652S1911R	5433U1904R	1	7065S1912R	2911U1909R	1	7066S1912R	2912U1909R
Qty	SET SN	UNIT SN																																																															
1	8487E1901R	2959U1809R																																																															
1	8488E1901R	2979U1809R																																																															
1	9681E1901R	4628U1810R																																																															
1	9682E1901R	4629U1810R																																																															
1	9683E1901R	4672U1810R																																																															
1	9684E1901R	4677U1810R																																																															
1	6347E1905R	8399U1901R																																																															
1	6348E1905R	8400U1901R																																																															
1	6349E1905R	8401U1901R																																																															
1	6625E1905R	8403U1901R																																																															
1	6626E1905R	8404U1901R																																																															
1	0358S1907R	0632U1902																																																															
1	0359S1907R	0633U1902R																																																															
1	3563S1909R	5455U1904R																																																															
1	5404S1911R	9464U1907R																																																															
1	5988S1911R	9470U1907R																																																															
1	6651S1911R	5432U1904R																																																															
1	6652S1911R	5433U1904R																																																															
1	7065S1912R	2911U1909R																																																															
1	7066S1912R	2912U1909R																																																															

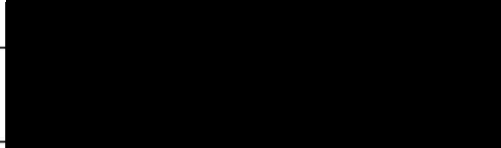
1	7067S1912R	2913U1909R
1	7068S1912R	2919U1909R
1	8768S2001R	2934U1909R
1	8769S2001R	2935U1909R
1	3549S2004R	6983U1912R
1	3550S2004R	6984U1912R
1	3551S2004R	6985U1912R

MD30:

Qty	SET SN	UNIT SN
1	8965E1901R	0230U1807R
1	8966E1901R	0231U1807R
1	8967E1901R	0232U1801R
1	8968E1901R	0233U1801R
1	3126S2004R	1237U1908R
1	0247E1902R	2410U1803R

2 Reason for Field Safety Corrective Action (FSCA)	
2.	<p>1. Description of the product problem</p> <p>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.</p>
2.	<p>2. Hazard giving rise to the FSCA</p> <p>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.</p>
2.	<p>3. Probability of problem arising</p> <p>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.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>none</p>

3. Type of Action to mitigate the risk		
3.	1. Action To Be Taken by the User <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None	
	Device must be returned to the following address: Nouvag GmbH Dental und Medizintechnik Schulthaisstrasse 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 <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> 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	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

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