

## DoC - DECLARATION OF CONFORMITY



### CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

<b>DOCUMENT NUMBER</b>	1240-KE-MDR-016	<b>REVISION LEVEL</b>	01	<b>PAGE NO</b>	Page 1 of 1
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<b>Manufacturer:</b>	Dentsply DeTrey GmbH De-Trey-Str. 1 78467 Konstanz Germany Single registration number (SRN): DE-MF-00005905
<b>Authorized UK-representative:</b>	Dentsply IH Ltd, The Heights. Building 3, Weybridge KT13 0NY
<b>PRODUCT CODE / CATALOGUE NUMBER</b>	<b>NAME</b>
606.20.110	AH Plus Standard Package
606.20.118	AH Plus Jet Refill
606.20.115	AH Plus Jet Starter Kit
<b>Classification and Rules (EU)</b>	EU class: The medical device AH-Plus is classified as Class IIa according to Rule 8 and Rule 19 of Annex VIII of MDR 2017/745
<b>Basic UDI-DI :</b>	++D010EFM02PZ
<b>Intended purpose:</b>	Permanent Root Canal Sealer
<p>WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF</p> <ul style="list-style-type: none"> <li>- THE REGULATIONS EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX.</li> </ul> <p>ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>	
<b>Common specifications applied</b>	N/A
<b>EC Certificate</b>	EC certificate number: G10 021108 0032 Rev. 00 Notified Body Name: TÜV SÜD Product Service GmbH Notified Body Address: Ridlerstrasse 65 80339 München Germany Notified Body Id: 0123

Konstanz, 26.02.2024

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 Grischka Friedrich  
 Senior Manager  
 Quality Assurance & Regulatory Compliance