

## DoC - DECLARATION OF CONFORMITY



### CONSUMABLE GROUP QUALITY SYSTEM FORM

<b>DOCUMENT NUMBER</b>	DOC-MDR-027-1	<b>REVISION LEVEL</b>	02	<b>PAGE NO</b>	Page 1 of 1
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Manufacturer: Dentsply DeTrey GmbH	Dentsply DeTrey GmbH De-Trey-Str. 1 78467 Konstanz Germany Single registration number (SRN): DE-MF-00005905
Authorized EU-representative:	N/A
<b>PRODUCT CODE / CATALOGUE NUMBER</b>	<b>NAME</b>
60607050	ChemVarnish Refill 1xbottle a 12,5ml
Classification and Rules	The medical device ChemVarnish is classified as class I according to Rule 5 of Annex VIII, MDR
Basic UDI-DI	++D010ACC06LN
Intended purpose: ChemVarnish is recommended to protect glass ionomer restorations from moisture contamination and dehydration during or immediately after setting.	
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH ANNEXES II and III. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
Common Standards applied:	DIN EN ISO 13485:2016 DIN EN ISO 14971:2013 DIN EN ISO 10993-1:2010 DIN EN 1041:2013 DIN EN 1641:2010 DIN EN 15223-1:2017
Technical standards ref.:	ISO 7405:2008+ A1 2013
EC certificate :	N/A

Konstanz, 2021-06-24

Grischka Friedrich  
 Senior Manager Quality Assurance & Regulatory Compliance

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