

## DoC - DECLARATION OF CONFORMITY



## CONSUMABLE GROUP QUALITY SYSTEM FORM

DOCUMENT NUMBER	DOC-MDR-023	REVISION LEVEL	02	PAGE NO	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>
605.78.320	Aquasil Soft Putty Standard Pack
605.78.321	Aquasil Soft Putty Economy Pack
605.78.328	Aquasil Soft Putty
605.78.332	Aquasil Hard Putty Standard Pack
605.78.333	Aquasil Hard Putty Economy Pack
Classification and Rules	The medical device Aquasil Soft Putty / Aquasil Hard Putty ist classified as class I according to Rule 5 of Annex VIII, MDR
Basic UDI-DI	++D010IMP02TD
Intended purpose: Aquasil Soft Putty / Aquasil Hard Putty are very high viscosity precision impression materials based on quadrafunctional hydrophilic siloxanes.	
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 1041:2013-12 DIN EN 1641:2010-02 ISO 10993-1:2018-08 DIN EN ISO 14971:2013-04 DIN EN ISO 15223-1:2017-04
Technical standards ref.:	DIN-EN ISO 7405:2019-03
EC certificate :	N/A

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Grischka Friedrich  
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