

DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1240-DOC-052	REVISION LEVEL	07	PAGE NO	Page 1 of 1
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Manufacturer:	Dentsply DeTrey GmbH De-Trey-Str. 1 78467 Konstanz Germany Single registration number (SRN): DE-MF-00005905
Authorized EU-representative:	N/A
Authorized UK-representative:	Dentsply IH Ltd. The Heights Building 3 Weybridge KT13 ONY United Kingdom
PRODUCT CODE / CATALOGUE NUMBER	NAME
60604202	Dyract Refill Package A2
60604203	Dyract Refill Package A3
60604204	Dyract Refill Package A3,5
60604205	Dyract Refill Package A4
60604206	Dyract Refill Package B1
60604208	Dyract Refill Package B3
Classification and Rules (EU)	EU class: The medical Devices are classified as Class IIa according to Rule 8 of Annex IX, MDD
Basic UDI-DI :	++D010FIM01QX
EMDN code / description :	Q01010103, Dental Restorative Materials, Composites
GMDN code / description :	35870, Dental Restorative Material Composites
Intended purpose:	Dyract® restorative is a light-curing restorative material for all cavity classes in front and posterior teeth. Dyract® restorative combines the fluoride release of glass-ionomer materials with the strength and aesthetics of a light-curing composite
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF	
<ul style="list-style-type: none"> - THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH THE ANNEX II excluding 4. - ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. - THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. 	
External references applied	N/A
EC Certificate	G1 021108 0031 Rev. 00 TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Germany ID number of NB: 0123
UK Certificate	N/A

Konstanz, 01.03.2023

Grischka Friedrich,
Senior Manager Quality Assurance & Regulatory
Compliance

FORM NO	8000-FM-008-05	REVISION LEVEL	5
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