

DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	Dentsply DeTrey GmbH De-Trey-Str. 1 78467 Konstanz Germany		
Authorized EU-representative:	n.a.		
PRODUCT CODE / CATALOGUE NUMBER	NAME	Classification	Rule*
606.04.901	Dyract eXtra Refill Shade A2	Ila	8
606.04.902	Dyract eXtra Refill Shade A3	Ila	8
606.04.903	Dyract eXtra Refill Shade A3.5	Ila	8
606.04.904	Dyract eXtra Refill Shade A4	Ila	8
606.04.905	Dyract eXtra Refill Shade B1	Ila	8
606.04.906	Dyract eXtra Refill Shade B3	Ila	8
606.04.907	Dyract eXtra Refill Shade C2	Ila	8
606.04.908	Dyract eXtra Refill Shade C3	Ila	8
606.04.909	Dyract eXtra Refill Shade O-A2	Ila	8
606.04.910	Dyract eXtra Refill Shade O-B3	Ila	8
606.04.210	Dyract XP Starter Kit	Ila	8
606.04.275	Dyract XP Refill Shade A2	Ila	8
606.04.276	Dyract XP Refill Shade A3	Ila	8
606.04.277	Dyract XP Refill Shade A3.5	Ila	8
606.04.278	Dyract XP Refill Shade B1	Ila	8
606.04.631	Dyract Posterior+ Refill	Ila	8
606.04.632	Dyract Posterior+ Eco Package	Ila	8
Classification rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC		
WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF 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.			
Harmonized Standards applied:	DIN EN ISO 13485:2016 DIN EN ISO 14971:2013 DIN EN ISO 10993-1:2010-04 DIN EN 1041:2013-12 DIN EN 1641:2010-02		
Technical standards ref.:	DIN EN ISO 7405:2008 + A1:2013 DIN EN ISO 4049:2009		
EC certificate:	According to annex II excluding (4) of the Directive 93/42/EEC G1 021108 0031 Rev. 00 TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Germany ID number of Notified Body: 0123		

Dentsply DeTrey GmbH
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Konstanz, January 15, 2020

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