

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*
606.67.240	Prime&Bond NT Refill	Ila	8
606.67.253	Prime&Bond NT Promotion	Ila	8
606.67.273	Prime&Bond NT Export Refill	Ila	8
606.67.225	Spectrum Bond	Ila	8
606.67.198	Applicator Tip Refill (100)	I	5
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		
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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