

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*
606.05.348	Spectrum TPH C3 Zhermack Syringe	Ila	8
606.05.349	Spectrum TPH B3 Zhermack Syringe	Ila	8
606.05.352	Spectrum TPH A2 Zhermack Syringe	Ila	8
606.05.353	Spectrum TPH A3 Zhermack Syringe	Ila	8
606.05.354	Spectrum TPH A3,5 Zhermack Syringe	Ila	8
606.05.355	Spectrum TPH B1 Zhermack Syringe	Ila	8
606.05.356	Spectrum TPH B2 Zhermack Syringe	Ila	8
606.05.357	Spectrum TPH OA2 Zhermack Syringe	Ila	8
606.05.358	Spectrum TPH OA3,5 Zhermack Syringe	Ila	8
606.05.359	Spectrum TPH A1 Zhermack Syringe	Ila	8
Classification rules acc.:	Classification according to ANNEX IX OF THE Council Directive 93/42/EEC of 14. June 1993 about medical device.		
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 ANNEXES II excluding 4 OF THE DIRECTIVE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DEDECLARATION OF CONFORMITY.			
Harmonized Standards applied:	EN 1041:2013 EN 1641:2010 EN ISO 10993:2010 EN ISO 15223-1:2017 EN ISO 13485:2016 EN ISO 14971:2013		
Technical standards ref.:	EN ISO 7405:2008 + A1:2013 EN ISO 4049:2010		
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		

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