Dentsply Sirona Restorative

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

Manufacturer:	Dentsply DeTrey GmbH De-Trey-Str. 1 78467 Konstanz
Authorized EU-representative:	n.a.

PRODUCT CODE / CATALOGUE NUMBER	NAME	Classification	Rule*
607.01.910A	Neo Spectra ST flow Compula Risk Free Trial Kit	IIa	8
607.01.930	Neo Spectra ST flow Compula Discovery Kit	IIa	8
607.01.910	Neo Spectra ST flow Compula Intro Kit	IIa	8
607.01.911	Neo Spectra ST flow Compula Refill A1	IIa	8
607.01.912	Neo Spectra ST flow Compula Refill A2	IIa	8
607.01.913	Neo Spectra ST flow Compula Refill A3	IIa	8
607.01.914	Neo Spectra ST flow Compula Refill A4	IIa	8
607.01.915	Neo Spectra ST flow Compula Refill A3.5	IIa	8
607.01.916	Neo Spectra ST flow Compula Refill BW	IIa	8
607.01.917	Neo Spectra ST flow Compula Refill E1	IIa	8
607.01.918	Neo Spectra ST flow Compula Refill D1	IIa	8
607.01.919	Neo Spectra ST flow Compula Refill D3	IIa	8
607.01.931	Neo Spectra ST flow Syringe Discovery Kit	IIa	8
607.01.920	Neo Spectra ST flow Syringe Intro Kit	IIa	8
607.01.920A	Neo Spectra ST flow Syringe Risk Free Trial Kit	IIa	8
607.01.921	Neo Spectra ST flow Syringe Refill A1	IIa	8
607.01.922	Neo Spectra ST flow Syringe Refill A2	IIa	8
607.01.923	Neo Spectra ST flow Syringe Refill A3	IIa	8
607.01.925	Neo Spectra ST flow Syringe Refill A3.5	IIa	8
607.01.924	Neo Spectra ST flow Syringe Refill A4	IIa	8
607.01.926	Neo Spectra ST flow Syringe Refill BW	IIa	8
607.01.928	Neo Spectra ST flow Syringe Refill D1	IIa	8
607.01.929	Neo Spectra ST flow Syringe Refill D3	IIa	8
607.01.927	Neo Spectra ST flow Syringe Refill E1	IIa	8
607.01.932	Neo Spectra ST flow Syringe Tips Refill	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 DIREECTIVE 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.

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Harmonized Standards applied:	EN ISO 13485 :2016 EN ISO 14971 :2012 EN 1041:2013 EN 1641:2009 EN ISO 10993-1:2010 EN ISO 15223-1:2017
Technical standards ref.:	EN ISO 7405:2013
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

KE-099-03

Dentsply DeTrey GmbH
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Konstanz, January 15, 2020

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