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. Brunel Way Stonehouse Gloucestershire GL10 3GB United Kingdom

PRODUCT CODE / CATALOGUE NUMBER	NAME
Neo Spectra ST	
Compules	
607.01.979	Neo Spectra ST HV Discovery Kit
607.01.970	Neo Spectra ST HV Intro Kit
607.01.970A	Neo Spectra ST HV Risk Free Kit
607.01.971	Neo Spectra ST HV Refill A1
607.01.972	Neo Spectra ST HV Refill A2
607.01.973	Neo Spectra ST HV Refill A3
607.01.974	Neo Spectra ST HV Refill A4
607.01.975	Neo Spectra ST HV Refill A3.5
607.01.976	Neo Spectra ST HV Refill BW
607.01.879	Neo Spectra ST LV Discovery Kit
607.01.870	Neo Spectra ST LV Intro Kit
607.01.870A	Neo Spectra ST LV Risk Free Kit
607.01.871	Neo Spectra ST LV Refill A1
607.01.872	Neo Spectra ST LV Refill A2
607.01.873	Neo Spectra ST LV Refill A3
607.01.874	Neo Spectra ST LV Refill A4
607.01.875	Neo Spectra ST LV Refill A3.5
607.01.876	Neo Spectra ST LV Refill BW
607.01.944	Neo Spectra ST Effects Discovery Kit
607.01.940	Neo Spectra ST Effects Intro Kit
607.01.941	Neo Spectra ST Effects Refill E1
607.01.942	Neo Spectra ST Effects Refill D 1
607.01.943	Neo Spectra ST Effects Refill D3
Syringes	
607.01.980	Neo Spectra ST HV Intro Kit
607.01.990	Neo Spectra ST HY Eco Refill
607.01.981	Neo Spectra ST HV Refill A1
607.01.982	Neo Spectra ST HV Refill A2
607.01.983	Neo Spectra ST HV Refill A3
607.01.984	Neo Spectra ST HV Refill A4
607.01.985	Neo Spectra ST HV Refill A3.5
607.01.986	Neo Spectra ST HV Refill BW
607.01.880	Neo Spectra ST LV Intro Kit
607.01.890	Neo Spectra ST LV Syringe Eco Kit
607.01.881	Neo Spectra ST LV Refill A1
607.01.882	Neo Spectra ST LV Refill A2
607.01.883	Neo Spectra ST LV Refill A3
607.01.884	Neo Spectra ST LV Refill A4
607.01.885	Neo Spectra ST LV Refill A3.5
607.01.950	Neo Spectra ST Effects Intro Kit
607.01.951	Neo Spectra ST Effects Refill E1
607.01.952	Neo Spectra ST Effects Refill D1
607.01.953	Neo Spectra ST Effects Refill D3
Classification and Rules (EU and UK)	EU class: The medical Devices are classified as Class IIa according to Rule 8 of Annex IX, MDD

Basic UDI-DI :	**++D010FIM03R3**
EMDN code / description :	Q01010103, Dental Restorative Materials, Composites
GMDN code / description :	35870, Dental Composite
Intended purpose:	Neo Spectra™ ST and Neo Spectra™ ST Effects are nano-ceramic, light-cured, radiopaque, universal composites based on the novel SphereTEC® filler technology indicated for both, direct and indirect restorations. The spherical, granulated filler technology called SphereTEC® leads to a ball-bearing effect that takes the handling properties of Neo Spectra™ ST and Neo Spectra™ ST Effects to the next level
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.	
External references (Common Specifications, Standards, Regulations) applied	N/A
EC Certificate Set N/A if class I device(s) Complete all lines for other classes.	G1 021108 0031 Rev. 00 TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Germany ID number of NB: 0123
UK Certificate Set N/A if class I device(s) Complete all lines for other classes.	N/A

Konstanz, 25.08.2025

Grischka Friedrich
Senior Manager QA