

	<b>Form (FOR)</b>	NOV-RA-FOR-0226
	EC Declaration of Conformity	Revision: 2

## EC Declaration of Conformity

**Manufacturer**                      Novatech SA  
Z.I. Athélia III - 1058, Voie Antiope  
13705 La Ciotat CEDEX,  
France

**Medical Device**                      **NOVATECH® GSS™**  
*See REF-s below*

**Device Classification**              Class IIb  
Rule 8

**MD Code / GMDN Code**            0203 / 46977

**Notified Body**                      DQS Medizinprodukte GmbH  
August-Schanz-Str. 21  
60433 Frankfurt am Main  
Germany  
  
Identification Number: 0297

**CE Marking First Applied**        6 December 2010

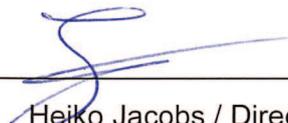
Novatech SA declares on its own responsibility that the above mentioned product meets the provisions of Council Directive 93/42/EEC for Medical Devices.

The conformity has been assessed according to Annex II excluding Section 4 of MDD 93/42/EEC [Certificate No. 170773598] and EN ISO 13485 [Certificate No. 170763138].

We herewith declare that the manufacturer is exclusively responsible for issuing the declaration of conformity.

This declaration of conformity is valid until the issuing of a revised version after change of a product or until 2024-05-26. whichever occurs first.

Berlin, 2021-01-07

  
\_\_\_\_\_  
Heiko Jacobs / Director QM

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REF	Product Name	Description
01TD1120	NOVATECH® GSS™ TD	TD 11 L 20
01TD1130	NOVATECH® GSS™ TD	TD 11 L 30
01TD1140	NOVATECH® GSS™ TD	TD 11 L 40
01TD1150	NOVATECH® GSS™ TD	TD 11 L 50
01TD1160	NOVATECH® GSS™ TD	TD 11 L 60
01TD1170	NOVATECH® GSS™ TD	TD 11 L 70
01TD1180	NOVATECH® GSS™ TD	TD 11 L 80
01TD1220	NOVATECH® GSS™ TD	TD 12 L 20
01TD1230	NOVATECH® GSS™ TD	TD 12 L 30
01TD1240	NOVATECH® GSS™ TD	TD 12 L 40
01TD1250	NOVATECH® GSS™ TD	TD 12 L 50
01TD1260	NOVATECH® GSS™ TD	TD 12 L 60
01TD1270	NOVATECH® GSS™ TD	TD 12 L 70
01TD1280	NOVATECH® GSS™ TD	TD 12 L 80
01TD1330	NOVATECH® GSS™ TD	TD 13 L 30
01TD1340	NOVATECH® GSS™ TD	TD 13 L 40
01TD1350	NOVATECH® GSS™ TD	TD 13 L 50
01TD1360	NOVATECH® GSS™ TD	TD 13 L 60
01TD1370	NOVATECH® GSS™ TD	TD 13 L 70
01TD1380	NOVATECH® GSS™ TD	TD 13 L 80
01TD1430	NOVATECH® GSS™ TD	TD 14 L 30
01TD1440	NOVATECH® GSS™ TD	TD 14 L 40
01TD1450	NOVATECH® GSS™ TD	TD 14 L 50

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01TD1460	NOVATECH® GSS™ TD	TD 14 L 60
01TD1470	NOVATECH® GSS™ TD	TD 14 L 70
01TD1480	NOVATECH® GSS™ TD	TD 14 L 80
01TD1530	NOVATECH® GSS™ TD	TD 15 L 30
01TD1540	NOVATECH® GSS™ TD	TD 15 L 40
01TD1550	NOVATECH® GSS™ TD	TD 15 L 50
01TD1560	NOVATECH® GSS™ TD	TD 15 L 60
01TD1570	NOVATECH® GSS™ TD	TD 15 L 70
01TD1580	NOVATECH® GSS™ TD	TD 15 L 80
01TD1590	NOVATECH® GSS™ TD	TD 15 L 90
01TD15100	NOVATECH® GSS™ TD	TD 15 L 100
01TD15110	NOVATECH® GSS™ TD	TD 15 L 110
01TD1630	NOVATECH® GSS™ TD	TD 16 L 30
01TD1640	NOVATECH® GSS™ TD	TD 16 L 40
01TD1650	NOVATECH® GSS™ TD	TD 16 L 50
01TD1660	NOVATECH® GSS™ TD	TD 16 L 60
01TD1670	NOVATECH® GSS™ TD	TD 16 L 70
01TD1680	NOVATECH® GSS™ TD	TD 16 L 80
01TD1690	NOVATECH® GSS™ TD	TD 16 L 90
01TD16100	NOVATECH® GSS™ TD	TD 16 L 100
01TD16110	NOVATECH® GSS™ TD	TD 16 L 110
01TD1840	NOVATECH® GSS™ TD	TD 18 L 40
01TD1850	NOVATECH® GSS™ TD	TD 18 L 50
01TF1230	NOVATECH® GSS™ TF	TF 12 L 30



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01TF1240	NOVATECH® GSS™ TF	TF 12 L 40
01TF1250	NOVATECH® GSS™ TF	TF 12 L 50
01TF1260	NOVATECH® GSS™ TF	TF 12 L 60
01TF1270	NOVATECH® GSS™ TF	TF 12 L 70
01TF1280	NOVATECH® GSS™ TF	TF 12 L 80
01TF1330	NOVATECH® GSS™ TF	TF 13 L 30
01TF1340	NOVATECH® GSS™ TF	TF 13 L 40
01TF1350	NOVATECH® GSS™ TF	TF 13 L 50
01TF1360	NOVATECH® GSS™ TF	TF 13 L 60
01TF1370	NOVATECH® GSS™ TF	TF 13 L 70
01TF1430	NOVATECH® GSS™ TF	TF 14 L 30
01TF1440	NOVATECH® GSS™ TF	TF 14 L 40
01TF1450	NOVATECH® GSS™ TF	TF 14 L 50
01TF1460	NOVATECH® GSS™ TF	TF 14 L 60
01TF1470	NOVATECH® GSS™ TF	TF 14 L 70
01TF1530	NOVATECH® GSS™ TF	TF 15 L 30
01TF1540	NOVATECH® GSS™ TF	TF 15 L 40
01TF1550	NOVATECH® GSS™ TF	TF 15 L 50
01TF1560	NOVATECH® GSS™ TF	TF 15 L 60
01TF1570	NOVATECH® GSS™ TF	TF 15 L 70
01TF1580	NOVATECH® GSS™ TF	TF 15 L 80
01TF1590	NOVATECH® GSS™ TF	TF 15 L 90
01TF15100	NOVATECH® GSS™ TF	TF 15 L 100



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01TF15110	NOVATECH® GSS™ TF	TF 15 L 110
01TF1640	NOVATECH® GSS™ TF	TF 16 L 40
01TF1650	NOVATECH® GSS™ TF	TF 16 L 50
01TF1660	NOVATECH® GSS™ TF	TF 16 L 60
01TF1670	NOVATECH® GSS™ TF	TF 16 L 70
01TF1680	NOVATECH® GSS™ TF	TF 16 L 80
01TF1690	NOVATECH® GSS™ TF	TF 16 L 90
01TF16100	NOVATECH® GSS™ TF	TF 16 L 100
01TF1840	NOVATECH® GSS™ TF	TF 18 L 40
01TF1850	NOVATECH® GSS™ TF	TF 18 L 50
01TF1860	NOVATECH® GSS™ TF	TF 18 L 60
01TF1870	NOVATECH® GSS™ TF	TF 18 L 70
01TF1880	NOVATECH® GSS™ TF	TF 18 L 80
01TF1890	NOVATECH® GSS™ TF	TF 18 L 90
01TF18100	NOVATECH® GSS™ TF	TF 18 L 100
01TF18110	NOVATECH® GSS™ TF	TF 18 L 110
01TF2040	NOVATECH® GSS™ TF	TF 20 L 40
01TF2050	NOVATECH® GSS™ TF	TF 20 L 50
01TF2060	NOVATECH® GSS™ TF	TF 20 L 60
01TF2070	NOVATECH® GSS™ TF	TF 20 L 70
01TF2080	NOVATECH® GSS™ TF	TF 20 L 80
01TF2090	NOVATECH® GSS™ TF	TF 20 L 90
01TF20100	NOVATECH® GSS™ TF	TF 20 L 100



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01TF20110	NOVATECH® GSS™ TF	TF 20 L 110
01ST121012	NOVATECH® GSS™ ST	ST 12-10-12 L 15-20-15
01ST141214	NOVATECH® GSS™ ST	ST 14-12-14 L 15-20-15
01ST151315	NOVATECH® GSS™ ST	ST 15-13-15 L 15-20-15
01ST161416	NOVATECH® GSS™ ST	ST 16-14-16 L 15-20-15
01ST181618	NOVATECH® GSS™ ST	ST 18-16-18 L 15-20-15
01DST141214	NOVATECH® GSS™ ST	ST 14-12-14 L 7.5-20-7.5
01DST161416	NOVATECH® GSS™ ST	ST 16-14-16 L 7.5-20-7.5
01DST181618	NOVATECH® GSS™ ST	ST 18-16-18 L 7.5-20-7.5
01BD1020	NOVATECH® GSS™ BD	BD 10 L 20
01BD1030	NOVATECH® GSS™ BD	BD 10 L 30
01BD1040	NOVATECH® GSS™ BD	BD 10 L 40
01BD1050	NOVATECH® GSS™ BD	BD 10 L 50
01BD1060	NOVATECH® GSS™ BD	BD 10 L 60
01BD1070	NOVATECH® GSS™ BD	BD 10 L 70
01BD1120	NOVATECH® GSS™ BD	BD 11 L 20
01BD1130	NOVATECH® GSS™ BD	BD 11 L 30
01BD1140	NOVATECH® GSS™ BD	BD 11 L 40
01BD1150	NOVATECH® GSS™ BD	BD 11 L 50
01BD1160	NOVATECH® GSS™ BD	BD 11 L 60
01BD1170	NOVATECH® GSS™ BD	BD 11 L 70
01BD1220	NOVATECH® GSS™ BD	BD 12 L 20



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01BD1230	NOVATECH® GSS™ BD	BD 12 L 30
01BD1240	NOVATECH® GSS™ BD	BD 12 L 40
01BD1250	NOVATECH® GSS™ BD	BD 12 L 50
01BD1260	NOVATECH® GSS™ BD	BD 12 L 60
01BD1270	NOVATECH® GSS™ BD	BD 12 L 70
01BD1280	NOVATECH® GSS™ BD	BD 12 L 80
01Y121010	NOVATECH® GSS™ Y	Y 12-10-10 L 70-50-50
01Y141010	NOVATECH® GSS™ Y	Y 14-10-10 L 110-50-50
01Y141010V1	NOVATECH® GSS™ Y	Y 14-10-10 L 40-30-30
01Y151212	NOVATECH® GSS™ Y	Y 15-12-12 L 110-50-50
01Y151212V1	NOVATECH® GSS™ Y	Y 15-12-12 L 40-30-30
01Y151212V2	NOVATECH® GSS™ Y	Y 15-12-12 L 50-30-30
01Y161313	NOVATECH® GSS™ Y	Y 16-13-13 L 110-50-50
01Y161313V1	NOVATECH® GSS™ Y	Y 16-13-13 L 40-30-30
01Y161313V2	NOVATECH® GSS™ Y	Y 16-13-13 L 50-30-30
01Y181414	NOVATECH® GSS™ Y	Y 18-14-14 L 110-50-50
01OKI130910	NOVATECH® GSS™ OKI	OKI 13-09-10 L 40-17-35