

EC Declaration of Conformity

according to Annex II of the Medical Device Directive 93/42/EEC

We, the manufacturer **JOTEC GmbH**
Lotzenäcker 23
72379 Hechingen, Germany

herewith declare under sole responsibility that the medical device

FlowNit

FlowNit Bioseal

FlowWeave

FlowWeave Bioseal

Textile Vascular Graft

Class III-product according to 93/42/EEC Annex IX, Rule 8

is in accordance with all requirements of the Medical Device Directive 93/42/EEC which are applicable.

This declaration was issued based on the EC Certificate, Annex Rev. 0 dated 24.03.2021 (Certificate Registration No. 50736-16-08) and EC Design Examination Certificate, Annex Rev. 0 dated 25.05.2021 (Certificate-registration No. 50736-53-A6).

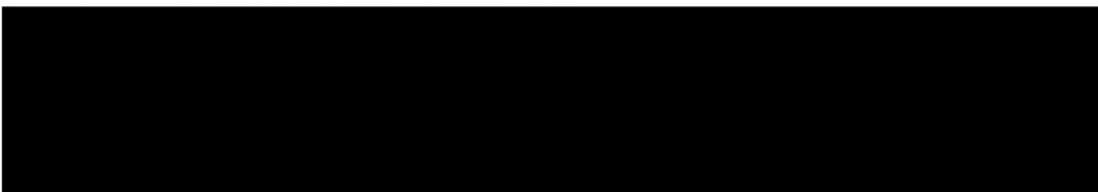
Notified Body:

DEKRA Certification GmbH, Handwerkstr. 15, 70565 Stuttgart, Germany, ID No. 0124

Date of the first declaration: 29.10.2004

Date of redeclaration: 25.05.2021

This declaration is valid until 26.05.2024



General Manager
JOTEC GmbH
Hechingen, 25.05.2021

Product Manager

Annex to the EC Declaration of Conformity for the Medical Device

FlowNit, FlowNit Bioseal, FlowWeave, FlowWeave Bioseal

Product Nomenclature

35 <u>ST</u> 1506	Product group 30 = FlowNit 35 = FlowNit Bioseal 40 = FlowWeave 45 = FlowWeave Bioseal
35 ST 1506	Configuration ST = Straight tube BI = Bifurcation (only FlowNit / FlowNit Bioseal)
35ST 15 06	For ST: Length [cm] (100cm = 00) For BI: Diameter body [mm]
35ST15 06	For ST = Diameter [mm] For BI = Diameter legs [mm]

Variation

Variations result from the configuration (straight tubes / bifurcations), length and diameter.

Tubes:	
Length	15 cm – 100 cm
Diameter	6 mm – 38 mm

Bifurcations:	
Length	45 cm
Diameter (Ø _{body} x Ø _{legs}):	12 mm x 6 mm – 24 mm x 12 mm

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Product code and catalogue number

FlowNit Textile Vascular Graft

Catalogue No.	Length [cm]	Diameter [mm]
30BI1206	45	12x6
30BI1407	45	14x7
30BI1608	45	16x8
30BI1809	45	18x9
30BI2010	45	20x10
30BI2211	45	22x11
30BI2412	45	24x12
30ST1508	15	8
30ST3008	30	8
30ST6006	60	6
30ST6007	60	7
30ST6008	60	8
30ST6010	60	10
30ST6012	60	12
30ST6014	60	14
30ST6016	60	16
30ST6018	60	18
30ST6020	60	20
30ST6022	60	22
30ST6024	60	24
30ST0008	100	8
30ST0010	100	10

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FlowNit Bioseal Textile Vascular Graft

Catalogue No.	Length [cm]	Diameter [mm]
35BI1206	45	12x6
35BI1407	45	14x7
35BI1608	45	16x8
35BI1809	45	18x9
35BI2010	45	20x10
35BI2211	45	22x11
35BI2412	45	24x12
35ST1506	15	6
35ST1507	15	7
35ST1508	15	8
35ST1510	15	10
35ST1512	15	12
35ST1514	15	14
35ST1516	15	16
35ST1518	15	18
35ST1520	15	20
35ST1522	15	22
35ST1524	15	24
35ST3006	30	6
35ST3007	30	7
35ST3008	30	8
35ST3010	30	10
35ST3012	30	12
35ST3014	30	14
35ST3016	30	16
35ST3018	30	18
35ST3020	30	20
35ST3022	30	22
35ST3024	30	24
35ST4506	45	6
35ST4507	45	7
35ST6006	60	6
35ST6007	60	7
35ST6008	60	8
35ST6010	60	10
35ST6012	60	12
35ST6014	60	14
35ST0008	100	8
35ST0010	100	10

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FlowWeave Textile Vascular Graft

Catalogue No.	Length [cm]	Diameter [mm]
40ST3012	30	12
40ST3014	30	14
40ST3016	30	16
40ST3018	30	18
40ST3020	30	20
40ST3022	30	22
40ST3024	30	24
40ST6006	60	6
40ST6008	60	8
40ST6010	60	10
40ST6012	60	12
40ST6014	60	14
40ST6016	60	16
40ST6018	60	18
40ST6020	60	20
40ST6022	60	22
40ST6024	60	24
40ST6026	60	26
40ST6028	60	28
40ST6030	60	30
40ST6032	60	32
40ST6034	60	34
40ST6036	60	36
40ST6038	60	38

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FlowNit, FlowNit Bioseal, FlowWeave, FlowWeave Bioseal

FlowWeave Bioseal Textile Vascular Graft

Catalogue No.	Length [cm]	Diameter [mm]
45ST1508	15	8
45ST1510	15	10
45ST1512	15	12
45ST1514	15	14
45ST1516	15	16
45ST1518	15	18
45ST1520	15	20
45ST1522	15	22
45ST1524	15	24
45ST1526	15	26
45ST1528	15	28
45ST1530	15	30
45ST1532	15	32
45ST1534	15	34
45ST1536	15	36
45ST1538	15	38
45ST3006	30	6
45ST3008	30	8
45ST3010	30	10
45ST3012	30	12
45ST3014	30	14
45ST3016	30	16
45ST3018	30	18
45ST3020	30	20
45ST3022	30	22
45ST3024	30	24
45ST3026	30	26
45ST3028	30	28
45ST3030	30	30
45ST3032	30	32
45ST3034	30	34
45ST3036	30	36
45ST3038	30	38
45ST6006	60	6
45ST6008	60	8
45ST6010	60	10
45ST6012	60	12
45ST6014	60	14
45ST6016	60	16

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Catalogue No.	Length [cm]	Diameter [mm]
45ST6018	60	18
45ST6020	60	20
45ST6022	60	22
45ST6024	60	24
45ST6026	60	26
45ST6028	60	28
45ST6030	60	30
45ST6032	60	32
45ST6034	60	34
45ST6036	60	36
45ST6038	60	38