

Declaration of Conformity

Manufacturer : **SANYLEG S.r.l. a Socio Unico**

Via Albania 1/3
446042 Castel Goffredo (MN)
Italy

Medical Device: *Compression stockings and tights*

REF. Code: *See attachment (Technical File 01-DT 02-DT 03DT 04-DT)*

UDI DI BASE: *80332014001-DTDX*

UDI DI BASE: *80332014002-DTE6*

UDI DI BASE: *80332014003-DTED*

UDI DI BASE: *80332014004-DTEL*

Applicable Directives: *MDR 2017/745 concerning medical device)*

Classification (Annex VIII MDR 2017/745): *Class 1 (Rule 1)*

(Conformity Assessment procedure): *(Annex IX)*

Under our sole responsibility, we state that the above mentioned products meet all the applicable essential requirements of Annex I of the MDR 2017/745 and all the applicable standards.

(Applicable harmonized European standards)

(The list of the applicable standards is reported in Technical Files).

(The Manufacturer undertakes too keep available for the Competent Authorities the technical documentation quoted in Annex II of Directive the MDR 2017/745 for a period of at least five years after the last manufacture of the product.)



(Authorized/Responsible Person)

Date *02/08/2022*

Signed:

SANYLEG S.r.l.
PASSION FOR COMPRESSION A SOCIO UNICO
Via Albania 1/3
46042 CASTEL GOFFREDO (Mantova) ITALY
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Attachment to declaration of conformity

List of modifications of medical devices

REF.Code	Modification	Compression
T41	Open toe (closed toe) knee-high stockings	23-32 MMHG
T42	Open toe (closed toe) stockings	23-32 MMHG
T43	Open toe (closed toe) tights	23-32 MMHG
B12	Cotton knee-high stockings	14-16 MMHG
P21	Compression knee-high stockings	15-21 MMHG
P22	Cotton knee-high stockings	15-21 MMHG
P23	Compression stockings	15-21 MMHG
P24	Compression tights	15-21 MMHG
M31	Compression knee-high stockings	25-27 MMHG
M32	Cotton knee-high stockings	25-27 MMHG
M33	Compression stockings	25-27 MMHG
M34	Compression tights	25-27 MMHG
SANH61	Compression anti-thrombosis stockings	18-20 MMHG
B11	Compression knee-high stockings	10-14 MMHG
B13	Compression stockings	10-14 MMHG
B14	Compression tights	10-14 MMHG
T31	Open toe (closed toe) knee-high stockings	18-21 MMHG
T32	Open toe (closed toe) stockings	18-21 MMHG
T33	Open toe (closed toe) tights	18-21 MMHG
H62	Compression anti-thrombosis knee-high stockings	18-20 MMHG
H63	Compression anti-thrombosis stocking	18-20 MMHG
H51	Compression anti-thrombosis stockings	18-20 MMHG
H52	Compression anti-thrombosis knee-high stockings	18-20 MMHG
H53	Compression anti-thrombosis stocking	18-20 MMHG
D61	Diabetic socks	NONE

(Authorized Responsible Person)

Signed:

Date

02/08/2022

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