

EU Declaration of Conformity

Version: 0.0

We,

Cenefom Corp. (SRN No.: TW-MF-000012190)

Registered Address:

1F., No.50-5, Keyan Rd., Hsinchu Science Park, Zhunan Township, Miaoli County 35053, Taiwan

Manufacturer Address:

2F&3F., No.50-3, Keyan Rd., Hsinchu Science Park, Zhunan Township, Miaoli County 35053, Taiwan

being the manufacturer and having appointed

MedNet EC-REP GmbH (SRN No.: DE-AR-000000002)

Borkstrasse 10, 48163 Münster, Germany

as our authorized representative in the E.U. for the product : Ophthalmic Sponge & ENT Sponge

Product Name	Basic UDI-DI	MDN Code	EMDN Code	Class	classification rule(s)
Ophthalmic Sponge <ul style="list-style-type: none">PVA Spear: OP-ES SeriesEye Wick: OP-EW SeriesCorneal Light Shield: OP-CS SeriesLASIK Ring: OP-LR SeriesLASIK Eye Drain: OP-LRD SeriesWipe: OP-IW Series	471155292OPT6	1206	M040399	Is	Rule 5, Annex VIII of the MDR
ENT Sponge <ul style="list-style-type: none">Nasal Packing: NP SeriesEar PackEar WickEar Wick / Fenestrated	471155292ENTHD	1204	M040799	Is	Rule 5, Annex VIII of the MDR

*All model list reference attachment 1.

Here declare that the above devices are designed and manufactured under normal conditions to achieve the intended purpose and take sole responsibility by Cenefom Corp.

Cenefom Corp. complies with the conformity assessment procedure described in Regulation (EU) 2017/745 on Medical Devices Article 52 and Annex IX excluding chapter II under the supervision of DNV Product Assurance AS (Veritasveien 1, 1363 Høvik Country: Norway), a Notified Body authorized by the Competent Authority of Norwegian Ministry of Health and Social Affairs, and carrying Notified Body Number 2460.

EC certificate number: C580081

For the evaluation regarding the Class Is product safety aspects, the following standards were applied:

Harmonized standards:

EN ISO 13485:2016/A11:2021; EN ISO 14971:2019/A11:2021; EN ISO 10993-12:2021; EN ISO 11137-1:2015/A2:2019; EN ISO 11737-1: 2018/A1:2021; EN ISO11737-2:2020; EN ISO 15223-1:2021

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Non-harmonious standards:

ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-11:2017; ISO 10993-17:2002; ISO 10993-18:2020; ISO 11137-2:2013/Amd 1:2022; IEC 62366-1:2015/Amd 1:2020; ISO 20417:2021; EN ISO 11607-1:2020; ISO 11607-1:2019; EN ISO 11607-2:2020; ISO 11607-2:2020; ISO 14644-1:2015; EN ISO 10993-10:2023; ASTM F88 / F88M-15; ASTM F1929 -15; ASTM D3078 - 02(2021); ASTM D4169-22; ASTM D4991 - 07(2015); JIS L 1907:2010; CNS 12915; ASTM F1980-21; USP<151>

Done at: Cenefom Corp.

1F., No.50-5, Keyan Rd., Hsinchu Science Park, Zhunan Township, Miaoli County 35053, Taiwan

On: 16th May,2024

By: *Y. F. Hsiao*

Ya Fang Hsiao
PRRC, Cenefom Corp.

Ophthalmic Sponge

Cenefom Model	Royal Sponge Model	Anscare Model	Aktive Model	Anodyne Surgical Model	BTX surg Model	Specification
OP-ES01	OP-ES01	OS-011-1	A-0405	CE01-0101-1020	WI0001Y	(W)8mm x (L)72mm(55+17mm)
OP-ES02	OP-ES02	-	-	CE01-0101-0580	-	(W)8mm x (L)72mm(55+17mm)
OP-ES03	OP-ES03	-	-	-	-	(W)8mm x (L)72mm(55+17mm)
OP-ES04	OP-ES04	-	-	-	-	(W)8mm x (L)72mm(55+17mm)
OP-ES06	OP-ES06	OS-011-6	-	CE01-0101-0520	-	(W)8mm x (L)72mm(55+17mm)
OP-ES07	OP-ES07	-	-	-	-	(W)8mm x (L)72mm(55+17mm)
OP-ES08	OP-ES08	-	-	-	-	(W)8mm x (L)72mm(55+17mm)
OP-ES09	OP-ES09	-	-	-	-	(W)8mm x (L)17mm
OP-ES10	OP-ES10	-	-	-	-	(W)8mm x (L)17mm
OP-EW01	OP-EW01		-	CE01-0801-0220	-	(W)3mm x (L)220mm x (H)2mm
OP-EW02	OP-EW02		-	-	-	(W)3mm x (L)220mm x (H)2mm
OP-CS01	OP-CS01		-	CE01-0201-0120	-	(ID) ϕ 7mm x (H)2mm
OP-CS02	OP-CS02		-	CE01-0401-0120	-	(ID) ϕ 9mm x (H)2mm
OP-CS03	OP-CS03			-	-	(ID) ϕ 8mm x (H)2mm
OP-CS04	OP-CS04			-	-	(ID) ϕ 4mm x (H)2mm
OP-CS05	OP-CS05			-	-	(ID) ϕ 6mm x (H)2mm
OP-LR01	OP-LR01			CE01-2901-0120	-	(ID) ϕ 10mm x (OD) ϕ 14mm x (H)2mm
OP-LR02	OP-LR02			CE01-3001-0120	-	(ID) ϕ 12mm x (OD) ϕ 15.4mm x (H)2mm
OP-LRD01	OP-LRD01			CE01-2401-0120	-	(ID) ϕ 10mm x (L) 40.6mm x (H)2mm
OP-LRD02	OP-LRD02			CE01-2301-0120	-	(ID) ϕ 12mm x (L) 48.9mm x (H)2mm
OP-IW01	OP-IW01			CE01-1501-0120	-	(W)76.2mm x (L) 76.2 mm x (H)2mm
OP-IW02	OP-IW02			-	-	(W)76.2mm x (L) 76.2 mm x (H)1mm
OP-IW03	OP-IW03			-	-	(W)82.5mm x (L) 82.5 mm x (H)1mm
OP-IW04	OP-IW04			-	-	(W)30mm x (L) 30mm x (H)2mm
OP-IW05	OP-IW05			-	-	(W)83mm x (L) 83 mm x (H)2mm

ENT Sponge

Cenefom Model	HIMOSTA Model	Anscare Model	STIP Model	Specification
EP-0712S	-	-	-	D=7mm L=12mm
EP-0912S	-	-	-	D=9mm L=12mm
EP-0915S	-	-	-	D=9mm L=15mm
EP-0924S	-	-	-	D=9mm L=24mm
EP-1215S	-	-	-	D=12mm L=15mm
EP-1224S	-	-	-	D=12mm L=24mm
EP-1520S	-	-	-	D=15mm L=20mm
EP-0712W	-	-	-	D=7mm L=12mm
EP-0912W	-	-	-	D=9mm L=12mm
EP-0915W	-	-	-	D=9mm L=15mm
EP-0924W	-	-	-	D=9mm L=24mm
EP-1215W	-	-	-	D=12mm L=15mm
EP-1224W	-	-	-	D=12mm L=24mm
EP-1520W	-	-	-	D=15mm L=20mm
EP-0712	-	-	-	D=7mm L=12mm
EP-0912	EP-0912	-	-	D=9mm L=12mm
EP-0915	EP-0915	-	-	D=9mm L=15mm
EP-0924	-	-	-	D=9mm L=24mm
EP-1215	-	-	-	D=12mm L=15mm
EP-1224	-	-	-	D=12mm L=24mm
EP-1520	-	-	-	D=15mm L=20mm
EP-0712F	-	-	-	D=7mm L=12mm
EP-0912F	-	-	-	D=9mm L=12mm
EP-0915F	-	-	-	D=9mm L=15mm
EP-0924F	-	-	-	D=9mm L=24mm
EP-1215F	-	-	-	D=12mm L=15mm
EP-1224F	-	-	-	D=12mm L=24mm
EP-1520F	-	-	-	D=15mm L=20mm
NP-LS10	-	-	AS 452010	(L)45mm×(W)20mm×(H)10mm
NP-LS10S	NP-LS10S	NS-011-1	-	(L)45mm×(W)20mm×(H)10mm
NP-LS10W	-	-	AS 452010F	(L)45mm×(W)20mm×(H)10mm
NP-LS15	-	-	AS 452015	(L)45mm×(W)20mm×(H)15mm
NP-LS15S	NP-LS15S	NS-012-1	-	(L)45mm×(W)20mm×(H)15mm
NP-LS15W	-	-	AS 452015F	(L)45mm×(W)20mm×(H)15mm
NP-LS15ST	NP-LS15ST	NS-013-2	-	(L)45mm×(W)20mm×(H)15mm
NP-LS15WT	-	-	AS 452015CF	(L)45mm×(W)20mm×(H)15mm
NP-LL10	-	-	AS 802010	(L)80mm×(W)20mm×(H)10mm
NP-LL10S	NP-LL10S	-	-	(L)80mm×(W)20mm×(H)10mm
NP-LL10W	-	-	AS 802010F	(L)80mm×(W)20mm×(H)10mm
NP-LL15	NP-LL15	-	AS 802015	(L)80mm×(W)20mm×(H)15mm
NP-LL15S	NP-LL15S	-	-	(L)80mm×(W)20mm×(H)15mm
NP-LL15W	-	-	AS 802015F	(L)80mm×(W)20mm×(H)15mm
NP-LL15ST	NP-LL15ST	-	-	(L)80mm×(W)20mm×(H)15mm
NP-LL15WT	-	-	AS 802015CF	(L)80mm×(W)20mm×(H)15mm
NP-ML10	-	-	-	(L)80mm×(W)20mm×(H)10mm

ENT Sponge

Cenefom Model	HIMOSTA Model	Anscare Model	STIP Model	Specification
NP-ML10S	-	NS-014-1	-	(L)80mm×(W)20mm×(H)10mm
NP-ML10W	-	-	-	(L)80mm×(W)20mm×(H)10mm
NP-ML15	-	NS-016-1	-	(L)80mm×(W)20mm×(H)15mm
NP-ML15S	-	NS-015-1	-	(L)80mm×(W)20mm×(H)15mm
NP-ML15W	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-ML15ST	-	NS-017-2	-	(L)80mm×(W)20mm×(H)15mm
NP-ML15WT	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-PL10	-	-	-	(L)80mm×(W)20mm×(H)10mm
NP-PL10S	-	-	-	(L)80mm×(W)20mm×(H)10mm
NP-PL10W	-	-	-	(L)80mm×(W)20mm×(H)10mm
NP-PL15	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-PL15S	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-PL15W	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-PL15ST	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-PL15WT	-	-	-	(L)80mm×(W)20mm×(H)15mm
NP-EL10	-	-	-	(L)100mm×(W)25mm×(H)10mm
NP-EL10W	-	-	-	(L)100mm×(W)25mm×(H)10mm
NP-EL10S	-	-	-	(L)100mm×(W)25mm×(H)10mm
NP-EL15	-	-	AS 1002515	(L)100mm×(W)25mm×(H)15mm
NP-EL15S	NP-EL15S	NS-031-1	-	(L)100mm×(W)25mm×(H)15mm
NP-EL15W	-	-	AS 1002515F	(L)100mm×(W)25mm×(H)15mm
NP-ES15	-	-	AS 552515	(L)55mm×(W)25mm×(H)15mm
NP-ES15S	NP-ES15S	NS-032-1	-	(L)55mm×(W)25mm×(H)15mm
NP-ES15W	-	-	AS 552515F	(L)55mm×(W)25mm×(H)15mm
NP-EB15W	-	-	-	(L)100mm×(W)25mm×(H)15mm
NP-DL10	-	-	-	(L)80mm×(W)30mm×(H)10mm
NP-DL10S	NP-DL10S	NS-021-1	-	(L)80mm×(W)30mm×(H)10mm
NP-DL10W	-	-	AS 803010F	(L)80mm×(W)30mm×(H)10mm
NP-DL15	-	-	-	(L)80mm×(W)30mm×(H)15mm
NP-DL15S	NP-DL15S	NS-022-1	-	(L)80mm×(W)30mm×(H)15mm
NP-DL15W	-	-	AS 803015F	(L)80mm×(W)30mm×(H)15mm
NP-DL15ST	NP-DL15ST	NS-023-2	-	(L)80mm×(W)30mm×(H)15mm
NP-DL15WT	-	-	AS 803015CF	(L)80mm×(W)30mm×(H)15mm
NP-SL05S	-	-	-	(L)35mm×(W)12mm×(H)6mm
NP-SL05W	-	-	-	(L)35mm×(W)12mm×(H)6mm
NP-SL06S	NP-SL06S	NS-041-1	-	(L)35mm×(W)12mm×(H)6mm
NP-SL06W	-	-	AS 35126F	(L)35mm×(W)12mm×(H)6mm
NP-SL09S	NP-SL09S	NS-042-1	-	(L)35mm×(W)12mm×(H)9mm
NP-SL09W	-	-	AS 35129F	(L)35mm×(W)12mm×(H)9mm
NP-SL10S	-	-	-	(L)35mm×(W)12mm×(H)9mm
NP-SL10W	-	-	-	(L)35mm×(W)12mm×(H)9mm
NP-HM12	-	-	-	(W)5mm×(H)5mm
NP-HL15	-	-	-	(W)6mm×(H)6mm