

2-June-2022

Ver. 001/22 (EN)

EU DECLARATION OF CONFORMITY

This Declaration of conformity has been issued under the sole responsibility of the manufacturer:

NAISAL INDUSTRIES
Moma Kalan, Near Ugoki,
Model Town, 51050 SIALKOT (PAKISTAN)
Company Registration Number 5012244-0
Single Registration Number (SRN) PK-MF-000018935

NAISAL INDUSTRIES declares that the devices listed below meet the provisions of regulation (EU) 2017/0745 (as amended) of the European Parliament and of the Council concerning Medical Devices

NAISAL INDUSTRIES has implemented a quality system according EN ISO 13485:2016 and is holder of the corresponding certificate issued by Dynamex Certification Service with the Nr DCS/2000-A, on 15 November 2022.

NAISAL INDUSTRIES has appointed as Authorised Representative the company:

INSDINIA S.L.
Fastenrath 8 ,1^a,1^a
08035 BARCELONA (SPAIN)
Company Registration Number (NIF) B-55595797
Single Registration Number (SRN) ES-AR-000016769

For and Behalf of NAISAL INDUSTRIES:

Mr. Sajid Tarar

Naisal Industries



Partner

Laryngoscopes (reusable)

Intended use: A hand-held disposable device intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.

It has a handle containing batteries to power its light (a small built-in light bulb or fibreoptic light) for airway illumination, and a curved or straight blade of various designs and lengths that can be hinged/interchanged or integral.

Product code	UDI code	Product description	Classification under ANNEX VIII	GMDN code
Standard Illumination				
30.4203-000	8964003189563	Blade McIntosh Nr 00 standard illumination	Class I (rule 5)	46827
30.4203-00	8964003189570	Blade McIntosh Nr 0 standard illumination	Class I (rule 5)	46827
30.4203-01	8964003189587	Blade McIntosh Nr 1 standard illumination	Class I (rule 5)	46827
30.4203-02	8964003189594	Blade McIntosh Nr 2 standard illumination	Class I (rule 5)	46827
30.4203-03	8964003189600	Blade McIntosh Nr 3 standard illumination	Class I (rule 5)	46827
30.4203-04	8964003189617	Blade McIntosh Nr 4 standard illumination	Class I (rule 5)	46827
30.4203-05	8964003189624	Blade McIntosh Nr 5 standard illumination	Class I (rule 5)	46827
30.4221-000	8964003189631	Blade Miller Nr 00 standard illumination	Class I (rule 5)	46827
30.4221-00	8964003189648	Blade Miller Nr 0 standard illumination	Class I (rule 5)	46827
30.4221-01	8964003189655	Blade Miller Nr 1 standard illumination	Class I (rule 5)	46827
30.4221-02	8964003189662	Blade Miller Nr 2 standard illumination	Class I (rule 5)	46827
30.4221-03	8964003189679	Blade Miller Nr 3 standard illumination	Class I (rule 5)	46827
30.4221-04	8964003189686	Blade Miller Nr 4 standard illumination	Class I (rule 5)	46827
30.4225-01	8964003189693	Handle child standard illumination	Class I (rule 5)	46827
30.4225-02	8964003189709	Handle adult standard illumination	Class I (rule 5)	46827
Fiber Optic Illumination				
30.4243-000	8964003189716	Blade McIntosh Nr 00 fiber optic illumination	Class I (rule 5)	46827
30.4243-00	8964003189723	Blade McIntosh Nr 0 fiber optic illumination	Class I (rule 5)	46827
30.4243-01	8964003189730	Blade McIntosh Nr 1 fiber optic illumination	Class I (rule 5)	46827
30.4243-02	8964003189747	Blade McIntosh Nr 2 fiber optic illumination	Class I (rule 5)	46827
30.4243-03	8964003189754	Blade McIntosh Nr 3 fiber optic illumination	Class I (rule 5)	46827
30.4243-04	8964003189761	Blade McIntosh Nr 4 fiber optic illumination	Class I (rule 5)	46827
30.4243-05	8964003189778	Blade McIntosh Nr 5 fiber optic illumination	Class I (rule 5)	46827
30.4253-000	8964003189785	Blade Miller Nr 00 fiber optic illumination	Class I (rule 5)	46827
30.4253-00	8964003189792	Blade Miller Nr 0 fiber optic illumination	Class I (rule 5)	46827
30.4253-01	8964003189808	Blade Miller Nr 1 fiber optic illumination	Class I (rule 5)	46827
30.4253-02	8964003189815	Blade Miller Nr 2 fiber optic illumination	Class I (rule 5)	46827
30.4253-03	8964003189822	Blade Miller Nr 3 fiber optic illumination	Class I (rule 5)	46827
30.4253-04	8964003189839	Blade Miller Nr 4 fiber optic illumination	Class I (rule 5)	46827
30.4466-01	8964003189846	Handle adult fiber optic illumination	Class I (rule 5)	46827
30.4466-02	8964003189853	Handle child fiber optic illumination	Class I (rule 5)	46827

Containers and trays (reusable)

Intended use: Stainless Steel containers and trays for surgical instrumental storage and handling.

NAISAL INDUSTRIES Stainless-Steel containers and trays can be sterilized in autoclave.

Product code	UDI code	Product description	Classification under ANNEX VIII	GMDN code
Boxes				
88.120.16	In process	165x85x35 mm	Class I (rule 1)	12143
88.120.20	In process	200x100x60 mm	Class I (rule 1)	12143
88.120.22	In process	220x120x60 mm	Class I (rule 1)	12143
88.120.23	In process	230x130x50 mm	Class I (rule 1)	12143
88.120.26	In process	260x150x50 mm	Class I (rule 1)	12143
88.120.30	In process	280x140x60 mm	Class I (rule 1)	12143
88.120.50	In process	500x200x120 mm	Class I (rule 1)	12143
Instrument trays				
88.145.21	In process	210x160x10 mm	Class I (rule 1)	12143
88.145.24	In process	240x180x10 mm	Class I (rule 1)	12143
88.145.29	In process	290x190x10 mm	Class I (rule 1)	12143
Universal Instrument Trays				
88.146.22	In process	220x170x50 mm	Class I (rule 1)	12143
88.146.28	In process	300x175x30 mm	Class I (rule 1)	12143
88.146.30	In process	300x175x40 mm	Class I (rule 1)	12143
88.146.32	In process	300x200x50 mm	Class I (rule 1)	12143
88.146.35	In process	350x240x36 mm	Class I (rule 1)	12143
88.146.37	In process	400x300x50 mm	Class I (rule 1)	12143
88.146.42	In process	450x350x50 mm	Class I (rule 1)	12143
Kidney Trays				
88.139.20	In process	200x120x35 mm	Class I (rule 1)	12143
88.139.25	In process	250x140x40 mm	Class I (rule 1)	12143
88.139.30	In process	300x160x50 mm	Class I (rule 1)	12143

Bowls (reusable)

Intended use: Stainless Steel bowls for surgical general use.

NAISAL INDUSTRIES Stainless-Steel bowls can be sterilized in autoclave.

Product code	UDI code	Product description		Classification under ANNEX VIII	GMDN code
Bowls		$\varnothing \times H$			
88.130.04	In process	40 x 19 mm	(0,05 Liter)	Class I (rule 1)	15561
88.130.06	In process	61 x 30 mm	(0,07 Liter)	Class I (rule 1)	15561
88.130.08	In process	80 x 40 mm	(0,14 Liter)	Class I (rule 1)	15561
88.130.12	In process	116 x 50 mm	(0,35 Liter)	Class I (rule 1)	15561
88.130.13	In process	128 x 55 mm	(0,45 Liter)	Class I (rule 1)	15561
88.130.15	In process	147 x 65 mm	(0,70 Liter)	Class I (rule 1)	15561
88.130.16	In process	157 x 75 mm	(1,10 Liter)	Class I (rule 1)	15561
88.130.19	In process	187 x 85 mm	(1,60 Liter)	Class I (rule 1)	15561
Round bowls		$\varnothing \times H$			
88.133.22	In process	220 x 70 mm	(2,00 Liter)	Class I (rule 1)	15561
88.133.24	In process	255 x 115 mm	(3,50 Liter)	Class I (rule 1)	15561
88.133.25	In process	260 x 130 mm	(4,50 Liter)	Class I (rule 1)	15561
88.133.27	In process	275 x 115 mm	(5,00 Liter)	Class I (rule 1)	15561
88.133.29	In process	300 x 105 mm	(6,00 Liter)	Class I (rule 1)	15561
88.133.38	In process	400 x 150mm	(14,00 Liter)	Class I (rule 1)	15561

Tunning Forks (reusable)

Intended use: Tuning forks, are used by medical practitioners to assess a patient's hearing.

Product code	UDI code	Product description	Classification under ANNEX VIII	GMDN code
<i>Lucae tuning forks</i>				
11.181-00	In process	Lucae tuning fork C 128	Class I (rule 1)	32526
11.181-01	In process	Lucae tuning fork C 256	Class I (rule 1)	32526
11.181-02	In process	Lucae tuning fork C 512	Class I (rule 1)	32526
11.181-03	In process	Lucae tuning fork C 1024	Class I (rule 1)	32526
11.181-04	In process	Lucae tuning fork C 2048	Class I (rule 1)	32526
11.181-05	In process	Lucae tuning fork C 4096	Class I (rule 1)	32526
11.181-06	In process	Lucae tuning fork with cursor C 128	Class I (rule 1)	32526
<i>Hartmann tuning forks</i>				
11.180-00	In process	Hartmann tuning fork C 128	Class I (rule 1)	32526
11.180-01	In process	Hartmann tuning fork C 256	Class I (rule 1)	32526
11.180-02	In process	Hartmann tuning fork C 512	Class I (rule 1)	32526
11.180-03	In process	Hartmann tuning fork C 1024	Class I (rule 1)	32526
11.180-04	In process	Hartmann tuning fork C 2048	Class I (rule 1)	32526
11.180-05	In process	Hartmann tuning fork C 4096	Class I (rule 1)	32526

Percussion hammers (reusable)

Intended use: Percussion hammers are used to test deep tendon reflexes, also known as reflex or neurological hammers.

NAISAL INDUSTRIES percussion hammers allow accurate and effective testing of muscle stretch reflexes, superficial or cutaneous reflexes with the best possible patient comfort.

NAISAL INDUSTRIES percussion hammers handle can be sterilized in autoclave.

Product code	UDI code	Product description	Classification under ANNEX VIII	GMDN code
<i>Percussion Hammers</i>				
11.45	In process	Babinsky percussion hammer 22 cm	Class I (rule 1)	11950
11.46	In process	Taylor percussion hammer 20 cm	Class I (rule 1)	11950
11.50	In process	Buck percussion hammer 18 cm	Class I (rule 1)	11950

Ear syringes (reusable)

Intended use: Ear syringes are used to remove earwax plugs.

For this, pressure washings are carried out with lukewarm water, oil or some other cerumenolytic product. This technique should be performed by a healthcare professional as improper use can damage the eardrum or push the wax plug further.

NAISAL INDUSTRIES Ear syringes are made of sterilizable and reusable stainless steel.

Product code	UDI code	Product description	Classification under ANNEX VIII	GMDN code
<i>Ear Syringes (reusable)</i>				
1.001	In process	Ear siringe 50 cc	Class I (rule 5)	47569
1.002	In process	Ear siringe 100 cc	Class I (rule 5)	47569
1.003	In process	Ear siringe 150 cc	Class I (rule 5)	47569
1.004	In process	Ear siringe 200 cc	Class I (rule 5)	47569