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DECLARATION OF CONFORMITY

Legal Manufacturer and Manufacturing Site:

Teleflex Medical Sdn. Bhd.
Lot PT 2577, Jalan Perusahaan 4,
34600 Kamunting, Perak, Malaysia

Authorized Representative:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Place of Issuance: Teleflex Medical Sdn. Bhd.

We hereby declare that under our sole responsibility the attached list of products meet all applicable provisions of the Council Directives 93/42/EEC. All supporting documentation are retained at the premises of the manufacturer and may be accessed, where appropriate, directly from the manufacturer.

Notified Body: **DEKRA CERTIFICATION GmbH**

Handwerkstraße 15
D-70565 Stuttgart, Germany

Registration No.: 50076-16-08 (MDD 93/42/EEC, Annex II)
50076-17-07 (MDD 93/42/EEC, Annex V)

Notified Body ID-number: 0124

Expiry Date: 26.05.2024

Approval

Function	Name	Approval	Date of Issuance
Originator	Siti Nur Atikah Idayu Bt Norzali		11 Feb 2020
Regulatory Affairs	Chuah Siew See		11 Feb 2020
Quality Assurance	Lau Yee Fan		19 FEB 2020

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Change History

CRF#	Issue Date	Revision	Summary of Changes
N/A	03 Mar 2014	5	1) To change FORM format 2) To update Device Description according to label
N/A	22 May 2014	6	1) To update Expiry date of new certificate
N/A	11 Mar 2016	7	1) To add codes 185200XX and 185420XX. XX denotes size of Nasopharyngeal Airway
N/A	31 Mar 2016	8	1) To amend product codes 1230, 1231 and 1233 to 1230XX, 1231XX and 1233XX. XX denotes size of Nasopharyngeal Airway.
N/A	28 July 2016	9	1) To amend Conformity Pathway for Class Is products. 2) To add MD code.
N/A	27 Feb 2017	10	1) To remove obsolete code – 185200G
17-426	16 June 2017	11	1) To Change Form Format 2) To update Expiry date of new certificate
18-036	24 Jan 2018	12	1) To add new items (2412-10, 2412-11, 2412-12, 2412-13 and 2415-01)
18-253	05 May 2018	13	1) Supersede SOI-098/F1 to WI-F000178 following Global Document Template.
18-282	18 May 2018	14	1) To remove Tracheostomy Adaptor (2415-01) to another DOC (DC-M006)
COF20-049-2	05 Feb 2020	15	1) To update new certificate number 2) To update Expiry date of new certificate

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Attachment to Declaration of Conformity

Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
Nasal Cannula Adult Tube 2M10 Non Sterile	LOC28MA	N/A	IIa	2	35202	Annex II	MD 0101	01 Nov 2003
	LOC28MAS						MD 0101	
Nasal Cannula Infant Tube 2M10 Non Sterile	LOC28ME	N/A	IIa	2	35202	Annex II	MD 0101	01 Nov 2003
	LOC28MES						MD 0101	
Nasal Cannula Neonate Tube 2M10 Non Sterile	LOC28MN	N/A	IIa	2	35202	Annex II	MD 0101	01 Nov 2003
	LOC28MNS						MD 0101	
Nasal Cannula Small Adult / Teenager Tube 2M10 Non Sterile	LOC28MP	N/A	IIa	2	35202	Annex II	MD 0101	01 Nov 2003
Nasal Cannula Pediatrique Tube 2M10 Non Sterile	LOC28MPS	N/A	IIa	2	35202	Annex II	MD 0101	01 Nov 2003
Robertazzi Nasopharyngeal Airway	123020	20	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	123022	22					MD 0101	
	123024	24					MD 0101	
	123026	26					MD 0101	
	123028	28					MD 0101	
	123030	30					MD 0101	
	123032	32					MD 0101	
	123034	34					MD 0101	
	123036	36					MD 0101	
Robertazzi Nasopharyngeal Airway	123120	20	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	123122	22					MD 0101	
	123124	24					MD 0101	
	123126	26					MD 0101	
	123128	28					MD 0101	
	123130	30					MD 0101	
	123132	32					MD 0101	
	123134	34					MD 0101	
	123136	36					MD 0101	
PVC Nasopharyngeal Airway	123312	12	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	123314	14					MD 0101	
	123316	16					MD 0101	
	123318	18					MD 0101	

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
PVC Nasopharyngeal Airway	123320	20	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	123322	22					MD 0101	
	123324	24					MD 0101	
	123326	26					MD 0101	
	123328	28					MD 0101	
	123330	30					MD 0101	
	123332	32					MD 0101	
	123334	34					MD 0101	
	123336	36					MD 0101	
Nasopharyngeal Airway	125410	12-36	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
RUSCH Gold® Nasopharyngeal Airway with Adjustable Flange	185200	20-36	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
Robertazzi Nasopharyngeal Airway, yellow	185300	20-36	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
Wirupren® Nasopharyngeal Airway, Robertazzi pattern	185410	20-36	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
Wirupren® Nasopharyngeal Airway with Adjustable Flange	185420	12-36	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
Nasopharyngeal Airway with Adjustable Flange	18520020	20	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	18520022	22					MD 0101	
	18520024	24					MD 0101	
	18520026	26					MD 0101	
	18520028	28					MD 0101	
	18520030	30					MD 0101	
	18520032	32					MD 0101	
	18520034	34					MD 0101	
	18520036	36					MD 0101	
Nasopharyngeal Airway with Adjustable Flange	18542012	12	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	18542014	14					MD 0101	
	18542016	16					MD 0101	
	18542018	18					MD 0101	

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
Nasopharyngeal Airway with Adjustable Flange	18542020	20	Is	5	42422	Annex V, Annex VII	MD 0101	01 Nov 2003
	18542022	22					MD 0101	
	18542024	24					MD 0101	
	18542026	26					MD 0101	
	18542028	28					MD 0101	
	18542030	30					MD 0101	
	18542032	32					MD 0101	
	18542034	34					MD 0101	
	18542036	36					MD 0101	
HUDSON RCI® Comfort Flo® Plus Chin Strap	2412-10	N/A	Ila	2	35202	Annex II	MD 0101	17 Jan 2018
HUDSON RCI® Comfort Flo® Plus Cannula with Chin Strap	2412-11	Large	Ila	2	35202	Annex II	MD 0101	17 Jan 2018
	2412-12	Medium						
	2412-13	Small						

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