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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	3	1) To change FORM format 2) To update Device Description according to label
N/A	22 May 2014	4	1) To update Description for 5025 from Flexi Slip™ to Flexi-Slip™ 2) To update Expiry date of new certificate
N/A	04 Mar 2015	5	1) To update Description for a) 112680 from "Super Safety Clear Tracheal Tube for medium-term and long-term Intubation, oral/nasal" to "Super Safety Silk Tracheal Tube" b) 112682 from "Super Safety Silk Tracheal Tube for medium-term and long-term intubation, oral/nasal, Murphy eye" to "Super Safety Silk Tracheal Tube, Murphy eye" c) 672482 from "ENDOSOFT Endotracheal Tube, Low Pressure Cuff, Murphy" to "ENDOSOFT Tracheal Tube, Murphy" 2) To remove size 3.0 for 104202 3) To remove obsolete codes
N/A	05 Feb 2016	6	1) To add codes 1003820XX and 1120820XX. XX denotes size of ET tubes.
N/A	11 Mar 2016	7	1) To add codes 1001800XX, 1001810XX, 1003800XX, 1117800XX, 1117810XX, 1120800XX, 1124800XX, and 1124820XX. XX denotes size of ET tubes.
N/A	31 Mar 2016	8	1) To amend product codes 103902, 1500, 1700, 5025, 5045, and 5065 to 1039020XX, 1500XX, 1700XX, 5025XX, 5045XX, and 5065XX. XX denotes size of ET tubes.
N/A	23 June 2016	9	1) To amend Conformity Pathway for product Class Is. 2) To add MD code.
17-426	16 June 2017	10	1) To Change Form Format 2) To update Expiry date of new certificate
18-253	05 May 2018	11	1) Supersede SOI-098/F1 to WI-F000178 following Global Document Template.
19-203	13 Mar 2019	12	To add new code - 1701
COF20-049-2	05 Feb 2020	13	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
RUSCHELIT® Preformed Oral Tracheal Tube, Two Eyes without Cuff	100180	3.0-7.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
RUSCHELIT® Preformed Nasal Tracheal Tube, Two Eyes without Cuff	100181	3.0-6.5	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
RUSCHELIT® Safety Clear Tracheal Tube, oral/nasal	100380	2.0-10.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
RUSCHELIT® Safety Clear Tracheal Tube, oral/nasal	100382	2.0-7.5					MD 0101	
Curved Reinforced Endotracheal Tube, oral/nasal, Murphy Eye, High Volume, Low Pressure Cuff	103902035	3.5	Ila	5	46569	Annex II	MD 0101	02 Apr 2003
	103902040	4.0					MD 0101	
	103902045	4.5					MD 0101	
	103902050	5.0					MD 0101	
	103902055	5.5					MD 0101	
	103902060	6.0					MD 0101	
	103902065	6.5					MD 0101	
	103902070	7.0					MD 0101	
	103902075	7.5					MD 0101	
	103902080	8.0					MD 0101	
	103902085	8.5					MD 0101	
	103902090	9.0					MD 0101	
	103902095	9.5					MD 0101	
	103902100	10.0					MD 0101	
RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff	104201	3.0-10.0	Ila	5	46569	Annex II	MD 0101	01 Nov 2003
RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff, Murphy Eye	104202	3.5-10.0	Ila	5	46569	Annex II	MD 0101	01 Nov 2003
RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff and FlexiSlip Intubation Stylet	104203	3.0-10.0	Ila	5	46569	Annex II	MD 0101	10 Nov 2003

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff and FlexiSlip Intubation Stylet, Murphy Eye	104204	5.0-9.0	Ila	5	46569	Annex II	MD 0101	10 Nov 2003
RUSCHELIT® Edgar Tube (no cuff)	111380	2.5-6.0	Ila	5	46967	Annex II	MD 0101	27 Oct 2005
RUSCHELIT® Edgar Tube (cuffed)	111480	6.5-10.0	Ila	5	46967	Annex II	MD 0101	27 Oct 2005
RUSCHELIT® Preformed Oral Tracheal Tube, Cuffed, Oral, Murphy Eye	111780	3.5-9.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
RUSCHELIT® Preformed Nasal Tracheal Tube, Cuffed, Nasal, Murphy Eye	111781	3.5-8.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
RUSCHELIT® Nasal Safety Silk Tracheal Tube, nasal, with Cuff, Preformed, Murphy Eye	111782	3.0-8.0	Ila	5	46967	Annex II	MD 0101	23 July 2007
RUSCHELIT® Safety Clear Plus Tracheal Tube, oral/nasal, Cuffed	112080	5.0-10.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
	112082						MD 0101	
RUSCHELIT® Super Safety Clear Microlaryngeal Tube, oral/nasal	112460	4.0-6.0	Ila	5	46967	Annex II	MD 0101	08 Sept 2005
RUSCHELIT® Super Safety Clear Tracheal Tube, oral/nasal, Cuffed	112480	2.5-10.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
Flexiset Super Safety Clear Tracheal Tube, oral/nasal with Cuff and Insertion Aid	112481	5.0-9.0	Ila	5	37469	Annex II	MD 0101	01 Nov 2003
RUSCHELIT® Super Safety Clear Tracheal Tube, oral/nasal, Cuffed	112482	2.5-10.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
Super Safety Silk Tracheal Tube	112680	5.0-10.0	Ila	5	46967	Annex II	MD 0101	24 Aug 2005
Super Safety Silk Tracheal Tube, Murphy eye	112682	3.0-10.0	Ila	5	46967	Annex II	MD 0101	07 Aug 2006
RUSCHELIT® Non Kinking Tube (Oxford), Oral with Low Pressure Cuff	112880	7.0-10.0	Ila	5	46967	Annex II	MD 0101	08 Sept 2005

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
ENDONORM Endotracheal Tube, Pear-shaped, Preformed Cuff, Murphy	672282	5.0-10.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
ENDOSOFT Tracheal Tube, Murphy	672482	3.0-10.0	Ila	5	46967	Annex II	MD 0101	01 Nov 2003
Slick® Stylet Disposable Endotracheal Stylet	500	6	Is	5	37469	Annex V, Annex VII	MD 0101	01 Nov 2003
	750	8					MD 0101	
	1000R	10					MD 0101	
Slick Set® Uncuffed Endotracheal Tube and Stylet Set, oral/nasal	150020	2.0	Ila	5	37469	Annex II	MD 0101	01 Nov 2003
	150025	2.5					MD 0101	
	150030	3.0					MD 0101	
	150035	3.5					MD 0101	
	150040	4.0					MD 0101	
	150045	4.5					MD 0101	
	150050	5.0					MD 0101	
	150055	5.5					MD 0101	
Slick Set® Cuffed Endotracheal Tube and Stylet Set, oral/nasal	170050	5.0	Ila	5	37469	Annex II	MD 0101	01 Nov 2003
	170055	5.5					MD 0101	
	170060	6.0					MD 0101	
	170065	6.5					MD 0101	
	170070	7.0					MD 0101	
	170075	7.5					MD 0101	
	170080	8.0					MD 0101	
	170085	8.5					MD 0101	
	170090	9.0					MD 0101	
	170095	9.5					MD 0101	
	1700100	10.0					MD 0101	
Slick Set® Uncuffed Endotracheal Tube and Stylet Set, oral/nasal	170120	2.0	Ila	5	37469	Annex II	MD0101	01 Nov 2003
	170125	2.5					MD0101	
	170130	3.0					MD0101	
	170135	3.5					MD0101	
	170140	4.0					MD0101	
	170145	4.5					MD0101	
	170150	5.0					MD0101	
	170155	5.5					MD0101	

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RUSCH Flexislip Endotracheal Tube Stylet with Soft Distal Tip	503700	06-14	Is	5	37469	Annex V, Annex VII	MD 0101	01 Nov 2003
Flexi-Slip™ Endotracheal Tube Stylet with Soft Distal Tip	502501	6	Is	5	37469	Annex V, Annex VII	MD 0101	01 Nov 2003
	502503	10					MD 0101	
	502505	12					MD 0101	
	502507	14					MD 0101	
Flexi-Set Cuffed Endotracheal Tube and Stylet Set, oral/nasal	504550	5.0	IIa	5	37469	Annex II	MD 0101	01 Nov 2003
	504555	5.5					MD 0101	
	504560	6.0					MD 0101	
	504565	6.5					MD 0101	
	504570	7.0					MD 0101	
	504575	7.5					MD 0101	
	504580	8.0					MD 0101	
	504585	8.5					MD 0101	
	504590	9.0					MD 0101	
Flexi-Set Uncuffed Endotracheal Tube and Stylet Set, oral/nasal	506525	2.5	IIa	5	37469	Annex II	MD 0101	01 Nov 2003
	506530	3.0					MD 0101	
	506535	3.5					MD 0101	
	506540	4.0					MD 0101	
	506545	4.5					MD 0101	
	506550	5.0					MD 0101	
Preformed AGT Oral Endotracheal Tube uncuffed/plain - Murphy	100180030	3.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	100180035	3.5					MD 0101	
	100180040	4.0					MD 0101	
	100180045	4.5					MD 0101	
	100180050	5.0					MD 0101	
	100180055	5.5					MD 0101	
	100180060	6.0					MD 0101	
	100180065	6.5					MD 0101	
	100180070	7.0					MD 0101	
Preformed AGT Nasal Endotracheal Tube uncuffed/plain - Murphy	100181030	3.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	100181035	3.5					MD 0101	
	100181040	4.0					MD 0101	
	100181045	4.5					MD 0101	
	100181050	5.0					MD 0101	

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
Preformed AGT Nasal Endotracheal Tube uncuffed/plain - Murphy	100181055	5.5	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	100181060	6.0					MD 0101	
	100181065	6.5					MD 0101	
Endotracheal Tube oral/nasal uncuffed/plain - Magill	100380020	2.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	100380025	2.5					MD 0101	
	100380030	3.0					MD 0101	
	100380035	3.5					MD 0101	
	100380040	4.0					MD 0101	
	100380045	4.5					MD 0101	
	100380050	5.0					MD 0101	
	100380055	5.5					MD 0101	
	100380060	6.0					MD 0101	
	100380065	6.5					MD 0101	
	100380070	7.0					MD 0101	
	100380075	7.5					MD 0101	
Endotracheal Tube oral/nasal uncuffed/plain - Murphy	100382020	2.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	100382025	2.5					MD 0101	
	100382030	3.0					MD 0101	
	100382035	3.5					MD 0101	
	100382040	4.0					MD 0101	
	100382045	4.5					MD 0101	
	100382050	5.0					MD 0101	
	100382055	5.5					MD 0101	
	100382060	6.0					MD 0101	
	100382065	6.5					MD 0101	
	100382070	7.0					MD 0101	
	100382075	7.5					MD 0101	
Preformed AGT Oral Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff	111780035	3.5	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	111780040	4.0					MD 0101	
	111780045	4.5					MD 0101	
	111780050	5.0					MD 0101	
	111780055	5.5					MD 0101	
	111780060	6.0					MD 0101	
	111780065	6.5					MD 0101	
	111780070	7.0					MD 0101	
	111780075	7.5					MD 0101	

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
Preformed AGT Oral Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff	111780080	8.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	111780085	8.5					MD 0101	
	111780090	9.0					MD 0101	
Preformed AGT Nasal Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff	111781035	3.5	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	111781040	4.0					MD 0101	
	111781045	4.5					MD 0101	
	111781050	5.0					MD 0101	
	111781055	5.5					MD 0101	
	111781060	6.0					MD 0101	
	111781065	6.5					MD 0101	
	111781070	7.0					MD 0101	
	111781075	7.5					MD 0101	
	111781080	8.0					MD 0101	
Endotracheal Tube oral/nasal Magill, High Volume, Low Pressure Cuff	112080050	5.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	112080055	5.5					MD 0101	
	112080060	6.0					MD 0101	
	112080065	6.5					MD 0101	
	112080070	7.0					MD 0101	
	112080075	7.5					MD 0101	
	112080080	8.0					MD 0101	
	112080085	8.5					MD 0101	
	112080090	9.0					MD 0101	
	112080095	9.5					MD 0101	
Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff	112080100	10.0					MD 0101	
	112082050	5.0	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	112082055	5.5					MD 0101	
	112082060	6.0					MD 0101	
	112082065	6.5					MD 0101	
	112082070	7.0					MD 0101	
	112082075	7.5					MD 0101	
	112082080	8.0					MD 0101	
	112082085	8.5					MD 0101	
	112082090	9.0					MD 0101	
	112082095	9.5					MD 0101	
	112082100	10.0					MD 0101	

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RUSCHELIT® Safety Clear Tracheal Tube, oral/nasal, Magill	112480025	2.5	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	112480030	3.0					MD 0101	
	112480035	3.5					MD 0101	
	112480040	4.0					MD 0101	
	112480045	4.5					MD 0101	
	112480050	5.0					MD 0101	
	112480055	5.5					MD 0101	
	112480060	6.0					MD 0101	
	112480065	6.5					MD 0101	
	112480070	7.0					MD 0101	
	112480075	7.5					MD 0101	
	112480080	8.0					MD 0101	
	112480085	8.5					MD 0101	
	112480090	9.0					MD 0101	
	112480095	9.5					MD 0101	
	112480100	10.0					MD 0101	
RUSCHELIT® Safety Clear Tracheal Tube, oral/nasal, Murphy	112482025	2.5	IIa	5	46967	Annex II	MD 0101	01 Nov 2003
	112482030	3.0					MD 0101	
	112482035	3.5					MD 0101	
	112482040	4.0					MD 0101	
	112482045	4.5					MD 0101	
	112482050	5.0					MD 0101	
	112482055	5.5					MD 0101	
	112482060	6.0					MD 0101	
	112482065	6.5					MD 0101	
	112482070	7.0					MD 0101	
	112482075	7.5					MD 0101	
	112482080	8.0					MD 0101	
	112482085	8.5					MD 0101	
	112482090	9.0					MD 0101	
	112482095	9.5					MD 0101	
	112482100	10.0					MD 0101	

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