

Doc No.:	DC-M018-3	Rev. No.:	01
----------	-----------	-----------	----

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

For Use by Affiliates of Teleflex

This document contains proprietary information. It may not be reproduced without prior written approval.

>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Document #: WI-F000099	Revision#:00	Issue Date: 17 AUG 2017	Parent Document: WI-000043
------------------------	--------------	-------------------------	----------------------------

Doc No.:	DC-M018-3	Rev. No.:	01
----------	-----------	-----------	----

Change History

CRF#	Issue Date	Revision	Summary of Changes
19-131	01 Mar 2019	00	Initial release of DC – M018-3
COF20-049-3	05 Feb 2020	01	1) To update new certificate number 2) To update Expiry date of new certificate

For Use by Affiliates of Teleflex

This document contains proprietary information. It may not be reproduced without prior written approval.

>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Document #: WI-F000099	Revision#:00	Issue Date: 17 AUG 2017	Parent Document: WI-000043
------------------------	--------------	-------------------------	----------------------------

Doc No.:	DC-M018-3	Rev. No.:	01
----------	-----------	-----------	----

Attachment to Declaration of Conformity

Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RUSCH Brilliant Paediatric (Silicone) Balloon Catheter	170003	06-10	IIb	5	34917	Annex II	MD 0203	01 Nov 2003
RUSCH Brilliant Paediatric Tiemann (Silicone) Balloon Catheter	170004	08-10	IIb	5	34917	Annex II	MD 0203	24 Feb 2005
RUSCH Brilliant (Silicone) Balloon Catheter	170605	12-24	IIb	5	34917	Annex II	MD 0203	01 Nov 2003
	170630	16-26					MD 0203	
	170671	12-24					MD 0203	
PRECONNECTED Drainage System with Silicone Catheter and Silflate	171100	12-22	IIb	5	34917+58921	Annex II	MD 0203	01 Nov 2003
ProfilCath Preconnected Silicone Foley and Prefilled Syringe	851086	14-20	IIb	5	34917+58921	Annex II	MD 0203	03 Nov 2010
RUSCH Brilliant Tiemann (Silicone) Balloon Catheter	171305	12-24	IIb	5	34917	Annex II	MD 0203	10 Jan 2005
RUSCH Brilliant Profil Tiemann (Silicone) Balloon Catheter	171365	12-24	IIb	5	34917	Annex II	MD 0203	14 Jan 2005
RUSCH Brilliant ProfilCath AquaFlate Glycerine (100% Silicone) Balloon Catheter with pre-filled syringe	171505	12-24	IIb	5	34917	Annex II	MD 0203	14 Jan 2005
RUSCH Brilliant (Silicone) Balloon Catheter, 2 Way with Couvelaire Tip	172530	18-24	IIb	5	34917	Annex II	MD 0203	15 July 2005
RUSCH Brilliant Profil (Silicone) Balloon Catheter, 3 Way with Couvelaire Tip	173230	18-24	IIb	5	34930	Annex II	MD 0203	20 May 2005
RUSCH Brilliant Profil (Silicone) Balloon Catheter with Installation Lumen	173330	18-24	IIb	5	34930	Annex II	MD 0203	24 May 2005

For Use by Affiliates of Teleflex

This document contains proprietary information. It may not be reproduced without prior written approval.

>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Document #: WI-F000099	Revision#:00	Issue Date: 17 AUG 2017	Parent Document: WI-000043
------------------------	--------------	-------------------------	----------------------------

Doc No.:	DC-M018-3	Rev. No.:	01
----------	-----------	-----------	----

Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RUSCH ProfilCath Silicone Catheter for the Neobladder, 3 way	173420	20-22	IIb	5	34930	Annex II	MD 0203	01 Dec 2006
RUSCH Brillant Profil (Silicone) Balloon Catheter	173430	18-24	IIb	5	34930	Annex II	MD 0203	01 Nov 2003
RUSCH Brillant (Silicone) Balloon Catheter	173830	16-24	IIb	5	34930	Annex II	MD 0203	14 Jan 2005
RUSCH Brillant (Silicone) Balloon Catheter, 3 Way with Couvelaire Tip	173930	18-24	IIb	5	34930	Annex II	MD 0203	22 July 2005
RUSCH Brillant (Silicone) Balloon Catheter, 3 Way with Dufour Tip	174030	18-24	IIb	5	34930	Annex II	MD 0203	24 Aug 2005
RUSCH Brillant (Silicone) Balloon Catheter, 3 Way with Mercier Tip	174130	18-24	IIb	5	34930	Annex II	MD 0203	24 Aug 2005
RUSCH Brillant AquaFlate Glycerine Silicone Balloon Catheter with Pre-filled Syringe	178000	12-24	IIb	5	34917	Annex II	MD 0203	01 Nov 2003
	178001						MD 0203	
AquaFlate Glycerine Silicone Balloon Catheter with Pre-filled Syringe	178003	06-10	IIb	5	34917	Annex II	MD 0203	27 Oct 2005
	178004	08-10					MD 0203	
	178305	12-24					MD 0203	01 Nov 2003
RUSCH Sensor Tiemann (Series 400) Silicone Balloon Catheter for the Measuring of Temperature	178370	08-18	IIb	5	34917	Annex II	MD 0203	12 Sept 2012
RUSCH Sensor (Series 400) Silicone Balloon Catheter for the Measuring of Temperature	179360	08-18	IIb	5	34917	Annex II	MD 0104	29 Oct 2007
	179361						MD 0203	12 Sept 2012
RUSCH Silicone Hyperthermia Bladder Catheter	179373	14	IIa	5	34917	Annex II	MD 0101	08 Sept 2006

For Use by Affiliates of Teleflex

This document contains proprietary information. It may not be reproduced without prior written approval.

>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Document #: WI-F000099	Revision#: 00	Issue Date: 17 AUG 2017	Parent Document: WI-000043
------------------------	---------------	-------------------------	----------------------------

Doc No.:	DC-M018-3	Rev. No.:	01
----------	-----------	-----------	----

Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RUSCH CARE Brilliant Plus AquaFlate Silicone Balloon Catheter with Pre-filled Syringe	850081	12-24	IIB	5	34917	Annex II	MD 0203	01 Nov 2003
	850085						MD 0203	
	850084						MD 0203	05 Apr 2005
RUSCH CARE ProfilCath Plus AquaFlate Silicone Balloon Catheter with Pre-filled Syringe	850086	10-24	IIB	5	34917	Annex II	MD 0203	16 Feb 2005
	850088	12-24					MD 0203	
RUSCH SilFlate Pre-filled Syringe with 10% Aqueous Glycerine Solution	850550	10	IS	1	47017	Annex V, Annex VII	MD 0203	12 Dec 2003
Brilliant comfort Silicone Balloon Catheter with prefilled syringe	850900	12-24	IIB	5	34917	Annex II	MD 0203	26 Apr 2004
	850901						MD 0203	30 Apr 2004
RUSCH® Pediatric Foley Catheter 100% Silicone 2 Way	170003060	6	IIB	5	34917	Annex II	MD 0203	01 Nov 2003
RUSCH® 100% Silicone Foley Balloon Catheter	170003080	8	IIB	5	34917	Annex II	MD 0203	01 Nov 2003
	170003100	10					MD 0203	
RUSCH® 100% Silicone Foley Balloon Catheter	170605120	12	IIB	5	34917	Annex II	MD 0203	01 Nov 2003
	170605140	14					MD 0203	
	170605160	16					MD 0203	
	170605180	18					MD 0203	
	170605200	20					MD 0203	
	170605220	22					MD 0203	
	170605240	24					MD 0203	
	170605260	26					MD 0203	
RUSCH® 100% Silicone Foley Balloon Catheter	170630160	16	IIB	5	34917	Annex II	MD 0203	01 Nov 2003
	170630180	18					MD 0203	
	170630200	20					MD 0203	
	170630220	22					MD 0203	
	170630240	24					MD 0203	
	170630260	26					MD 0203	

For Use by Affiliates of Teleflex

This document contains proprietary information. It may not be reproduced without prior written approval.

>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Document #: WI-F000099	Revision#: 00	Issue Date: 17 AUG 2017	Parent Document: WI-000043
------------------------	---------------	-------------------------	----------------------------

Doc No.:	DC-M018-3	Rev. No.:	01
----------	-----------	-----------	----

Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
RUSCH® 100% Silicone Foley Balloon Catheter	171305120	12	IIb	5	34917	Annex II	MD 0203	10 Jan 2005
	171305140	14					MD 0203	
	171305160	16					MD 0203	
	171305180	18					MD 0203	
	171305200	20					MD 0203	
	171305220	22					MD 0203	
	171305240	24					MD 0203	
RUSCH® 100% Silicone Foley Balloon Catheter	173830160	16	IIb	5	34930	Annex II	MD 0203	14 Jan 2005
	173830180	18					MD 0203	
	173830200	20					MD 0203	
	173830220	22					MD 0203	
	173830240	24					MD 0203	

For Use by Affiliates of Teleflex

This document contains proprietary information. It may not be reproduced without prior written approval.

>>THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR CHECKING THE CURRENT ISSUE DATE BEFORE USING THIS DOCUMENT<<

Document #: WI-F000099	Revision#:00	Issue Date: 17 AUG 2017	Parent Document: WI-000043
------------------------	--------------	-------------------------	----------------------------