



## EC DECLARATION OF CONFORMITY

We, Inter-Med, Inc. located at 2200 South St., Racine, WI 53404 USA, ensure and declare that the products listed hereafter and marketed as medical devices are classified Class IIa, according to the criteria of the European directive 93/42 EEC (as amended by 2007/47/EC) on medical devices – Annex IX Classification Criteria – and meets the provisions of the directive which apply to them.

This declaration is based on the various technical documentations demonstrating compliance with essential requirements of Annex I – General Requirements – of the directive. Furthermore, the Inter-Med, Inc. Management system meets the requirements of 93/42/EEC Annex V 3.2 and ISO 13485 :2016.

Notified Body:	LNE / GMED
Notified Body Address:	1 rue Gaston Boissier Paris, France 75015
Number of the Notified Body:	0459
Designated Representative:	EMERGO EUROPE
Designated Representative Address:	Prinsessegracht 20 2514 AP, The Hague The Netherlands Tel: +31 (0)70 345 8570 Fax: +31 (0)70 346 7299

Date of Issue: March 29, 2021

Representative: Alex Johnson  
Quality Assurance / Regulatory Affairs Manager  
Inter-Med / Vista Dental Products  
2200 South St.  
Racine, WI 53404 USA

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits

5/19/2021

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**QT 7.4-6 Declaration of Conformity – CE Class Ila Products**

<b>Revision</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>	<b>H</b>			
<b>Change Request Number</b>	CCF256	CCF271	CCF270	CCF358	CCF400	CCF424			

TF	Medical Device Product Family	Medical Device Product Line	Medical Device Description	Medical Device Commercial Reference Number (SKU)	GMDN	Medical Device Class	Rule
TF100A	Dental Needle Tips	1/2" Bendable Applicator Tips	22ga - Black	315222	60366	Ila	6
TF100A	Dental Needle Tips	1/2" Bendable Applicator Tips	22ga - Black	315202	60366	Ila	6
TF100A	Dental Needle Tips	1/4" Bendable Applicator Tips	25ga-Orange	315225	60366	Ila	6
TF100A	Dental Needle Tips	1/4" Bendable Applicator Tips	25ga-Orange	315205	60366	Ila	6
TF100A	Dental Needle Tips	Blue-Flo	Blue-Flo Tips	316202	35697	Ila	6
TF100A	Dental Needle Tips	Blue-Flo	Blue-Flo Tips	316222	35697	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	16ga-White	315316	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	16ga-White	315306	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	20ga-Opaque Black	315320	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	20ga-Opaque Black	315330	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tip	25ga	315325	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tip	22ga	315322	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	Nordenta 22ga Prebent Tips	315322-32	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	Nordenta 25ga Prebent Tips	315325-32	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	Nordenta 25ga Prebent Tips	315335-32	60366	Ila	6
TF100A	Dental Needle Tips	Pre-Bent Tips	Nordenta 20ga Prebent Tips	315320-32	60366	Ila	6
TF100A	Dental Needle Tips	Spira-Flo™ Tips	Brush Tips	321450	60366	Ila	6
TF100A	Dental Needle Tips	Spira-Flo™ Tips	Brush Tips	321400	60366	Ila	6
TF100A	Dental Needle Tips	Stat-Flo Tips	19ga-Prebent (Yellow)	312100	60366	Ila	6
TF100A	Dental Needle Tips	Stat-Flo Tips	19ga-Prebent (Yellow)	312102	60366	Ila	6
TF100A	Dental Needle Tips	Stat-Flo™ Tips	19ga - Pre-bent (Yellow)	312105	60366	Ila	6
TF100A	Dental Needle Tips	Stat-Flo™ Tips	Nordenta Stat Flo Tips	312100-32	60366	Ila	6
TF100A	Dental Needle Tips	Stat-Flo™ Tips	Nordenta Stat Flo Tips	312102-32	60366	Ila	6
TF100B	Dental Needle Tips	Appl-Vac™ 3/4" Bendable Needle Tips	16ga - White	315116	64403	Ila	6
TF100B	Dental Needle Tips	Appl-Vac™ 3/4" Bendable Needle Tips	16ga - White	315016	64403	Ila	6
TF100B	Dental Needle Tips	Appl-Vac™ 3/4" Bendable Needle Tips	18ga - Pink	315018	64403	Ila	6
TF100B	Dental Needle Tips	Appl-Vac™ 3/4" Bendable Needle Tips	19ga - Brown	315019	64403	Ila	6



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TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	20ga - Yellow	315020	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	22ga - Black	315022	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	25ga - Blue	315025	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	18ga - Pink	315118	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	19ga - Brown	315119	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	20ga - Yellow	315120	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	22ga - Black	315122	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	25ga - Blue	315125	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	Nordenta 18ga 3/4" Tips	315018-32	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	Combo Kit - (20) each gauge	315510	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ 3/4" Bendable Needle Tips	Nordenta Appil-Vac 25ga 3/4" Tips	315025-32	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tips	23ga - Blue	315023	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tips	27ga - Yellow	315027	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tips	30ga - Purple	315030	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tips	23ga - Blue	315523	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tips	27ga - Yellow	315527	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Tip	30ga	315530	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tip	Nordenta 23ga Irrigating Tip	315023-32	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tip	Nordenta 27ga Irrigating Tip	315027-32	64403	Ila	6
TF100B	Dental Needle Tips	Appil-Vac™ Irrigating Tip	Nordenta 30ga Irrigating Tip	315030-32	64403	Ila	6
TF100B	Dental Needle Tips	Flexi-Glide™ Utility Tips	30ga - Opaque Black	406320	35697	Ila	6
TF100B	Dental Needle Tips	Flexi-Glide™ Utility Tips	30ga - Opaque Black	406360	35697	Ila	6
TF100B	Dental Needle Tips	Flexi-Glide™ Utility Tips	Nordenta 30ga Flexi-Glide Tips	406320-32	35697	Ila	6
TF100B	Dental Needle Tips	Flexi-Glide™ Utility Tips	25ga - Yellow	406520	35697	Ila	6
TF100B	Dental Needle Tips	Flexi-Glide™ Utility Tips	25ga - Yellow	406550	35697	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Appil-Vac™ Irrigating Tips	12cc Luer Lock Syringe with 23ga Tip	316113	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Appil-Vac™ Irrigating Tips	12cc Luer Lock Syringe with 27ga Tip	316117	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Appil-Vac™ Irrigating Tips	12cc Luer Lock Syringe with 30ga Tip	316119	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Appil-Vac™ Irrigating Tips	3cc Luer Lock Syringe with 23ga Tip	316133	64403	Ila	6





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TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Appli-Vac™ Irrigating Tips	3cc Luer Lock Syringe with 27ga Tip	316137	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Appli-Vac™ Irrigating Tips	3cc Luer Lock Syringe with 30ga Tip	316139	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Vista-Probe™ Irrigating Tips	12cc Luer Lock Syringe with 23ga Tip	316213	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Vista-Probe™ Irrigating Tips	12cc Luer Lock Syringe with 27ga Tip	316217	64403	Ila	6
TF100B	Dental Needle Tips	Pre-Tipped Syringes w/ Vista-Probe™ Irrigating Tips	12cc Luer Lock Syringe with 30ga Tip	316219	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Visco-Tip™ (50/cup)	312300	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Visco-Tip™ (20/cup)	312302	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Nordenta Visco Tips	312302-32	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	ES Minimal Waste BC Sealer tip (15/cup)	315304	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	BC RRM Retrograde Tips (15/cup)	311115	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Low waste flex flo tips (10 count)	FFT10	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Low waste flex flo tips (20 count)	FFT20	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Low waste flex flo tips (40 count)	FFT40	64403	Ila	6
TF100B	Dental Needle Tips	Visco-Tip	Flex tips (20 count)	KBCS1FT	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	23ga - Blue	315123	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	27ga - Yellow	315127	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	30ga - Purple	315130	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	23ga - Blue	315623	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	27ga - Yellow	315627	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	30ga - Purple	315630	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	Nordenta 30ga Probe Tips	315630-32	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	Nordenta 27ga Probe Tips	315127-32	64403	Ila	6
TF100B	Dental Needle Tips	Vista-Probe™ Irrigating Tips	Nordenta 30ga Probe Tips	315130-32	64403	Ila	6
TF100B	Disposable MTA Carriers	Disposable MTA Carriers	Disposable MTA Carriers 1.6mm	807015	64403	Ila	6
TF100B	Disposable MTA Carriers	Disposable MTA Carriers	Disposable MTA Carriers .99mm	807016	64403	Ila	6
TF100B	Disposable MTA Carriers	Disposable MTA Carriers	Disposable MTA Carriers .80mm	807017	64403	Ila	6
TF100B	Disposable MTA Carriers	Disposable MTA Carriers	Disposable MTA Carriers Variety Pack	807019	64403	Ila	6





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TF100B	Flexible Endodontic Irrigating Tips	NITI Tip	NITI Tips	405106	64403	Ila	6
TF100B	Flexible Endodontic Irrigating Tips	NITI Tips	NITI Tips	405108	64403	Ila	6
TF100B	Dental Needle Tips	NITI Tip	NITI Tips	405107	64403	Ila	6
TF100B	Flexible Endodontic Irrigating Tips	NITI Tips	Nordenta Short Niti	405107-32	64403	Ila	6
TF100B	Flexible Endodontic Irrigating Tips	NITI Tips	Nordenta Mixed Niti	405106-32	64403	Ila	6
TF100B	Flexible Endodontic Irrigating Tips	NITI Tips	Nordenta Long Niti	405108-32	64403	Ila	6
TF102A	Endodontic Brush	Rotational Utility Brush	Versa Brush	204300	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	480ml bottle	317011	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	120ml bottle	317001	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	Unit Dose	317002	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	Bulk Syringe	503700	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	Canal Pro EDTA - 500mL	317014-12	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	Canal Pro EDTA - 100mL	317017-12	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	480ml bottle	317011-9	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	R4+, 1 pack bottle, 100mL	317020-25	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	Nordenta 17% EDTA 480ml Bottle	317011-32	45500	Ila	6
TF103	Chelating Root Canal Cleaners	17% EDTA Solution	Nordenta 17% EDTA 120ml Bottle	317001-32	45500	Ila	6
TF103	Chelating Root Canal Cleaners	SmearOFF	16oz bottle	317111	45500	Ila	6
TF103	Chelating Root Canal Cleaners	SmearOFF	4oz bottle	317112	45500	Ila	6
TF103	Final Rinse Solutions	2% CHX	16oz bottle	317010	45500	Ila	6
TF103	Final Rinse Solutions	2% CHX	30mL bulk syringe	503750	45500	Ila	6
TF103	Final Rinse Solutions	2% CHX	1.2mL syringe kit	502450	45500	Ila	6



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TF103	Final Rinse Solutions	2% CHX	CanalPro CHX 2% - 500mL	503915-12	45500	Ila	6
TF103	Final Rinse Solutions	2% CHX	CanalPro CHX 2% - 100mL	503911-12	45500	Ila	6
TF103	Final Rinse Solutions	2% CHX	Largal+, 1 pack bottle, 100mL	317083-25	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	16oz bottle	503900	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	1.2mL syringe endodontic kit	502925	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	1.2mL syringe endodontic refill kit	503930	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	30mL bulk syringe	503850	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	30mL bulk syringe kit	503400	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	16oz. Bottle - Schein	503900-11	45500	Ila	6
TF103	Final Rinse Solutions	CHX-Plus	16oz. Bottle - CyberTech	503900-14	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	16oz. bottle - 6%	317008	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	16oz. bottle - 3%	317018	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	12cc Prefilled Syringes - 6%	502300	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	12cc Prefilled Syringes - 3%	502315	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	3cc Prefilled Syringes - 6%	502350	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	3cc Prefilled Syringes 3%	502355	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	16oz. bottle - 3%	317018-11	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	16oz. bottle - 3%	317018-14	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	CanalPro NaOCl 3% - 500mL	317015-12	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	CanalPro NaOCl 6% - 500mL	317005-12	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	16oz. bottle - 3%	317018-9	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	3% Sodium Hypochlorite - Parcan N, 3 pack bottles, 100mL	317031-25	45500	Ila	6



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TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	3% Sodium Hypochlorite – Parcan N, 1 pack bottles, 250mL	317050-25	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite	Nordenta 3% Sodium Hypochlorite 480ml Bottle	317018-32	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite ≤ 6% w/surface modifiers	16oz bottle Chlor-XTRA™	503800	45500	Ila	6
TF103	Sodium Hypochlorite Solutions	Sodium Hypochlorite ≤ 6% w/surface modifiers	3cc Prefilled Syringes Chlor-XTRA™	503825	45500	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Gel Standard Kit	502804	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Free Standard Kit	504600	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Gel Bulk Syringe Kit	503550	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Gel Bulk Syringe Refill	503555	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Free Bulk Syringe Refill	504660	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Free Bulk Syringe Kit	504650	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Gel Value Pack	502800	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Free Value Pack	504640	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick-Stat Liquid (30mL Bottle)	317120	46423	Ila	6
TF105	Retraction and Astringent Solutions	Tissue Management	Quick Stat Liquid (30mL Syringe)	504155	46423	Ila	6
TF112	Etchants	37% Phosphoric Acid Etch Gel	Best-Etch™ Standard Kit	502115	36153	Ila	6
TF112	Etchants	37% Phosphoric Acid Etch Gel	Best-Etch™ Bulk Etch Kit	502236	36153	Ila	6
TF112	Etchants	37% Phosphoric Acid Etch Gel	Best-Etch™ Bulk Syringe Refill	502230	36153	Ila	6
TF112	Etchants	37% Phosphoric Acid Etch Gel	Best-Etch™ Value Kit	502200	36153	Ila	6
TF112	Etchants	Porcelain Etch - 9.5% Hydrofluoric Acid Etch Gel	Porcelain Etch	502500	62474	Ila	6
TF112	Etchants	Porcelain Etch - 9.5% Hydrofluoric Acid Etch Gel	Porcelain Etch Refill	502510	62474	Ila	6
TF112	Etchants	Silane Bonding Resin	Silane Refill	502505	62474	Ila	6



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TF112	Adhesives	Surpass	Self-etching Adhesive System with Micro-brush Applicators	90000	34782	Ila	8
TF112	Adhesives	Surpass	Refill Bottle Set	90001	34782	Ila	8
TF112	Adhesives	Simplicity	Simplicity Kit	90400	34782	Ila	8
TF112	Adhesives	Simplicity	Refill Bottles	90402	34782	Ila	8
TF112	Adhesives	Superb	Superb Kit	SDL17	34782	Ila	8
TF112	Adhesives	Superb	Superb Refill Kit	SDL18	34782	Ila	8
TF112	Adhesives	REGEN Universal	Universal Adhesive Kit REGEN	90637	34782	Ila	8
TF112	Adhesives	REGEN Universal	Universal Refill Kit REGEN	90638	34782	Ila	8
TF112	Primers	Clean & Boost	Liquid 5 pack	90057	34782	Ila	6
TF112	Primers	Clean & Boost	Gel 5 pack	90417	34782	Ila	6
TF112	Primers	Desensimax	Desensimax Kit	90413	45232	Ila	6
TF112	Primers	Bondsever	Starter Kit	SDL16	45232	Ila	6
TF112	Primers	Interface	Interface Kit	90030	63626	Ila	8
TF112	Primers	ZrP	Bottle	90577	63626	Ila	6



