CE
0459

EC DECLARATION OF CONFORMITY

according to annex VII of MDD 93/42/EEC Council Directive of
14 June 1993 concerning medical devices

Inter-Med/Vista Dental Products ensures and declares 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 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
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Representative: Alex Johnson
Regulatory Affairs / Quality Assurance Manager
Inter-Med / Vista Dental Products
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Product Family	Product Line	Product Description	Vista SKU
Endodontic Agents and Solutions	3% Sodium Hypochlorite	Parcan N, 3 pack bottles, 100mL	317031-25
Endodontic Agents and Solutions	3% Sodium Hypochlorite	Parcan N, 1 pack bottle, 250mL	317050-25
Endodontic Agents and Solutions	2% Chlorhexidine Gluconate	R4+, 1 pack bottle, 100mL	317020-25
Endodontic Agents and Solutions	17% EDTA	Largal+, 1 pack bottle, 100mL	317093-25