

DoC - DECLARATION OF CONFORMITY

CONSUMABLE GROUP QUALITY SYSTEM FORM



DOCUMENT NUMBER	ECDOC-103	REVISION LEVEL	2	PAGE NO	Page 1 of 1
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Manufacturer:	GS Medical Packaging, Inc., 82 Akron Road Unit 2, Etobicoke, ON, M8W 1T2 Canada Single registration number (SRN) N/A				
Authorized EU- representative:	Emergo Europe, Prinsesegracht 20, 2514 AP, The Hague, The Netherlands				
PRODUCT CODE / CATALOGUE NUMBER	NAME				
83020	Assure Plus Pouches 10 x 16 (254mm x 406mm) Box of 200				
83080	Assure Plus Pouches 11 x 16 (279mm x 406mm) Box of 100				
83025	Assure Plus Pouches 12 x 18 (305mm x 457mm) Box of 100				
83001	Assure Plus Pouches 2.25 x 5 (57mm x 127mm) Box of 200				
83003	Assure Plus Pouches 2.75 x 10 (70mm x 255mm) Box of 200				
83000	Assure Plus Pouches 3.5 x 6.5 (89mm x 165mm) Box of 200				
83005	Assure Plus Pouches 3.5 x 10 (90mm x 255mm) Box of 200				
83075	Assure Plus Pouches 5.25 x 7.5 (133mm x 191mm) Box of 200				
83010	Assure Plus Pouches 5.25 x 11 (133mm x 279mm) Box of 200				
83045	Assure Plus Pouches 5.5 x 14 (140mm x 356mm) box of 200				
83015	Assure Plus Pouches 7.5 x 14 (191mm x 356mm) Box of 200				
	End of List				
Classification and Rules (MDR)	This product is classified as a Class I Medical Device under Annex VIII, Chapter III, Section 4.1 per Rule 1, non-invasive device under Regulation 2017/745.				
Basic UDI-DI	++D687STERILIPOUCHBE				
Intended purpose:	Sterilization pouches are intended for packaging of reusable medical devices which are to be terminally sterilized in their packaging by steam or ethylene oxide.				
WE HEREWITHE DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.					
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.					
Common Standards applied:	N/A				
Technical standards ref.:	Standard	Title			Compliance
	BS ISO 14971	Medical Devices - Application of Risk Management to Medical Devices			Full
	ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.			Full
BS EN 1641	Dentistry -- Medical devices for dentistry – Materials			Full	
EC certificate:	N/A				

Dentsply LLC, Professional Division, Trading as Sultan Healthcare, 1301 Smile Way, York, PA 17404 USA

Effective Date: May 26, 2021

Khyati Dave, Regulatory Affairs Manager

Date

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