

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM FORM					
DOCUMENT NUMBER	ECDOC-103	REVISION LEVEL	2	PAGE NO	Page 1 of 1

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, Prinsessegracht 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.			
<p>WE HEREWITH 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.</p> <p>THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>			
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

5/26/2021

Date

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