

INTRAORAL CAMERA SHEATH



Conformity & Regulatory Information

Generic Device Group	Barrier Sleeves						
Model	126 - Intraoral Camera Sheaths						
Regulation	Medical Device Regulation (EU) 2017/745						
Classification and Rule	Class I, Rule 5						
Basic UDI-DI	++D125BRSLEEVE2W						
Nomenclature	<table> <tr> <td>EMDN</td><td>T0399</td></tr> <tr> <td>GMDN</td><td>12535</td></tr> <tr> <td>UMDNS</td><td>16146</td></tr> </table>	EMDN	T0399	GMDN	12535	UMDNS	16146
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GMDN	12535						
UMDNS	16146						
Intended Use	Single use barrier sleeves intended to form a protective barrier on intraoral cameras, it is intended as a hygienic barrier to protect the contents and prevent cross-contamination.						
Indications of use	- For professional dental application only - Single use - Latex free (does not contain natural rubber latex)						
Other	Sheath size 220 x 55 mm						

Product Specification

Packaging Description	<table> <tr> <td>Primary</td><td>100 pcs/box</td></tr> <tr> <td>Secondary</td><td>36 boxes/case</td></tr> </table>	Primary	100 pcs/box	Secondary	36 boxes/case
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Secondary	36 boxes/case				
Packaging Languages	EN, PL, DE, FR, IT, ES, PT, FI, NO, SV, DA, RO, CS, EL, HU, LV, LT, SK, JA, ZH				
Composition	Low Density Polyethylene, paper				
Traceability	UDI				
Storage Conditions	Do not store in direct sunlight, store in a cool dry place				

Manufacturer Information

Manufacturer	Premium Plus (Dongguan) Ltd.	Manufacturer SRN	CN-MF-000038259
EU Representative	Premium Plus Poland sp. z o.o.	EU Representative SRN	PL-AR-000030110
UK Representative	Premium Plus UK Ltd.	Country of Manufacture	China

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