

**APPROVED BY:**

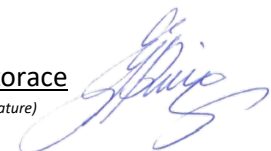
General Manager

R. Žurauskaitė - Storace

(Name, surname, signature)

2022-03-08

(date)



MEDICAL DEVICE SPECIFICATION	
Specification version No.	1
Purpose	The objective of this specification is to prescribe conditions which must i-SHINE comply with before it is released for distribution
Product type	Composite polishing paste
Basic UDI-DI	4772178ML11PMTQ
EMDN code	Q01010403, DENTAL ABRASIVE AND POLISHING MATERIALS
Class and rule according to (EU) 2017/745 on medical devices	Class I, rule 5
INTENDED USE	
Intended to restore/improve aesthetic appearance of restorable tooth; restore/maintain dental function of restorable tooth; protect biological structures of restorable tooth and adjacent tissues	
LEVEL OF USE	
For professional use in dentistry only	
PHYSICAL/CHEMICAL CHARACTERISTICS	
Appearance	Paste
Odour	Odourless
Colour	White
Shelf life	2 years
Composition	Glycerol, ultra-fine aluminium oxide particles, excipients
PACKAGE	
Sterility	N/A
Primary package	3ml syringe (contains 1g, 4g paste), with cap, PP/LDPE
Secondary package	Box, Cardboard
STORAGE	
Storage temperature	4-28°C
Storage conditions	Keep tightly closed in dry well-ventilated place Protect from direct sunlight and heat sources
Requirements for utilization	Dispose of contents/container as required by national regulatory requirements
PACKAGING	
ISHP1	4g polishing paste in syringe
ISHSP	1g polishing paste in syringe

Document history

Revision date	Change description	Established	Signature
2022.03.08	Printing Date	Project – Quality Manager Kristijonas Lotiukas	