


**Approved by:**

General Manager

 R. Žurauskaitė - Storace  
(signature)

2021-11-01

<b>MEDICAL DEVICE SPECIFICATION</b>	
<b>i-FASTE</b>	
Purpose	The objective of this specification is to prescribe conditions which must i-FASTE comply with before it is released for distribution
Product type	Tooth surface polishing paste
UMDNS name	Prophy pastes
UMDNS code	16699
UMDNS definition	Dental materials designed to clean and polish teeth by the dental care staff. These dental materials usually consist of a semisolid mixture (i.e., a paste or cream) comprising several abrasive compounds; some dental pastes include fluoride in their preparation. Prophylaxis pastes usually start out coarse and gradually break down into smaller particles as you clean, resulting in less abrasion to the dentin and enamel; they provide a high-luster enamel polish.
Class and rule according to (EU) 2017/745 on medical devices	Class I, rule 5
<b>INTENDED USE</b>	
Intended for cleaning and polishing the surface of the tooth during restorative and prophylactic dental treatment	
<b>LEVEL OF USE</b>	
For professional use in dentistry	
<b>PHYSICAL/CHEMICAL CHARACTERISTICS</b>	
Composing	One-component
Physical state	Paste
Appearance (coarseness, colour, odour)	Coarse, green, peppermint
	Medium, orange, orange
	Medium, reddish, cherry
	Medium, pearl white, bubble mint
	Medium, royal purple, mangosteen
	Fine, yellow, apple
Shelf life	3 years
Composition	Pumice, filler, water, colorant, odour additive
<b>PACKAGE</b>	
Sterility	N/A

Primary package	30ml cream pot (contains 10g paste sample, 30g paste), 90ml cream pot (contains 100g paste) with cap, PP/PP 2ml cup (contains 2g paste) with cover, PP/Foil
Secondary package	Box, Cardboard
<b>STORAGE</b>	
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
<b>PACKAGING</b>	
REF IFCSTP	10g paste coarse (sample)
REF IFCTP	30g paste coarse, peppermint, shade green, instruction for use
REF IFC100	100g paste coarse, peppermint, shade green, instruction for use
REF IFCD1	100x2g single dose cups, paste coarse, peppermint, shade green, instruction for use
REF IFMSTP	10g paste medium
REF IFMTP	30g paste medium, orange, shade orange, instruction for use
REF IFM100	100g paste medium, orange, shade orange, instruction for use
REF IFMD1	100x2g single dose cups, paste medium, orange, shade orange, instruction for use
REF IFFSTP	10g paste fine
REF IFFTP	30g paste fine, apple, shade yellow, instruction for use
REF IFF100	100g paste fine, apple, shade yellow, instruction for use
REF IFFD1	100x2g single dose cups, paste fine, apple, shade yellow, instruction for use
REF IFMB30	30g paste medium, bubble mint
REF IFMB100	100g paste medium, bubble mint
REF IFMB250	250g paste medium, bubble mint
REF IFMM30	30g paste medium, mangosteen
REF IFMM100	100g paste medium, mangosteen
REF IFMM250	250g paste medium, mangosteen
REF IFMC30	30g paste medium, cherry
REF IFMC100	100g paste medium, cherry
REF IFMC250	250g, paste medium, cherry
REF IFMCSP	2g paste medium, sample, cherry
REF IFMCSTP	10 g paste, sample, cherry
REF IFMMSP	2g, paste medium, sample, mangosteen
REF IFMMSTP	10g paste medium, sample, mangosteen

REF IFMBSP	2g paste medium, sample, bubble mint
REF IFMBSTP	10g paste medium, sample, bubble mint
REF IFMSK1	3x10g paste medium, sample (mangosteen, cherry, bubble mint)
REF IFMCD1	100x2g paste medium, cherry
REF IFMMD1	100x2g paste medium, mangosteen
REF IFMBD1	100x2g paste medium, bubble mint

Document history

Revision date	Change description	Established	Signature
2020-08-12	Printing date	Project – Quality Manager, Rūta Abramauskaitė	-
2021-03-26	Shift from MDD 93/42/EEC to EU MDR 2017/745 risk classification	Quality Manager (PTD), Justina Šiaučiūnaitė	-
2021-11-01	Added additional information REF	Quality Manager (PTD), Ieva Stočkutė	