

**Approved by:**

General Manager

 G. Dapkus

(signature)

2020-02-04

MEDICAL DEVICE SPECIFICATION	
i-CORE	
Specification version No.	2
Purpose	The objective of this specification is to prescribe conditions which must i-CORE comply with before it is released for distribution.
Medical device name	Dual curing core build-up and post cementation material
UMDNS name	16724
UMDNS code	Dental Materials, Restorative, Composite Resin
UMDNS definition	Restorative dental materials designed to be used as plastic fillings for in situ restoration of the appearance, structure and/or function of a patient's teeth. These restorative dental materials consist of a synthetic organic resin matrix in which a blend of particles (e.g., glass, quartz, silica) acting as fillers are dispersed. Composite resin restorative dental materials are supplied in a single-paste or in a two-paste system. They are usually strong, durable, easy to manipulate and shape. Composite resin restorative dental materials are placed in highly visible areas (e.g., the central incisors or any other teeth that can be seen when smiling) or in areas where conservation of tooth structure is a top priority. Heat-cured, self-cured, and light-cured composite resin restorative dental materials are available. They are used in dentists' offices.
Class and rule according to (EU) 2017/745 on medical devices	Class IIa, rule 8
INTENDED USE	
Indented for core build-up and post cementation	
LEVEL OF USE	
For professional use in dentistry	
PHYSICAL/CHEMICAL CHARACTERISTICS	
Composing	Two-component
Physical state	Paste (catalyst) / paste (base)
Shade	Yellowish (catalyst) / yellowish (base)
Odour	Specific
Flexural strength	Min. 50 MPa

Water sorption	Max. 40 µg/mm <sup>3</sup>
Water solubility	Max. 7.5 µg/mm <sup>3</sup>
Working time	Min. 90 sec
Setting time	Max. 10 min
Radio-opacity	Equal or greater than that of the same thickness of aluminium
Curing mode	Dual (light and chemical)
Shelf life	2 years
Composition	Catalyst paste: dental glass grinded, methacrylate mixture, photoinitiator, coinitiators, UV stabilizer, inhibitor, opacifier Base paste: dental glass grinded, methacrylate mixture, initiator, inhibitor, opacifier
<b>PACKAGE</b>	
Sterility	N/A
Primary package	Automix double syringe (PP) (contains 4.5g catalyst and 4.5g base) with plugger (PPH), static mixer (PP/POM) and tips (PE)
	Cartridge (PP) (contains 25g catalyst and 25g base) with piston (PE), cap (PP/PE) and mixer
Secondary package	Box, Cardboard
<b>STORAGE</b>	
Storage temperature	2-8°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. Small quantities can be disposed of together with the household waste. To safely dispose of excess of material, extrude unused portion from container and cure before disposal
<b>PACKAGING</b>	
REF ICOR1	9g syringe, 10 pcs automix tips, 10 pcs intraoral-root canal tips, 10psc endo tips, instructions for use
REF ICOR2	2x9g automix syringe, 20pcs automix tips, 10pcs intraoral-root canal tips, 10psc endo tips, instructions for use
REF ICOR3	50g cartridge, 25pcs automix tips, 25pcs intraoral-root canal tips, instructions for use

Prepared by:

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