



FAMI EU Declaration of conformity

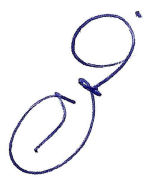
Manufacturer: FAMI – Fábrica de Artefatos Metalúrgicos Itá Ltda.
 Alameda São Caetano 2790
 09560-500 – São Caetano do Sul / SP – Brazil
 SRN: BR-MF-000039534

Authorized Representative: Easy Medical Device CommV
 Dendermondestraat 40-44
 2018 Antwerpen
 Belgium
 SRN: BE-AR-000011902

We, company FAMI – Fábrica de Artefatos Metalúrgicos Itá Ltda., Alameda São Caetano 2790, 09560-500, São Caetano do Sul/SP, Brazil, declare under our sole responsibility that the above-mentioned products to which this declaration refers is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.

This declaration of conformity is issued under the exclusive responsibility of the manufacturer.

Product Family: Sterilization Tray			
Product code	Name of device	Classification	Basic UDI-DI
136.111	FAMI Versius Endoscope Reprocessing Basket	Class – I, Rule – I	07899524533223
136.113	FAMI Processing Basket for the Versius Ultrasonic Dissector Transducer.	Class – I, Rule – I	07899524533483
124.111	Baskets for optics with removable lid – 290x80x50 mm for 1 optic	Class – I, Rule – I	07899524533100
124.112	Baskets for optics with removable lid – 460x80x50 mm for 1 optics	Class – I, Rule – I	07899524533131
124.113	Baskets for optics with removable lid – 670x80x50 mm for 1 optic	Class – I, Rule – I	07899524533230
124.114	Baskets for optics with removable lid –	Class – I, Rule – I	07899524533186

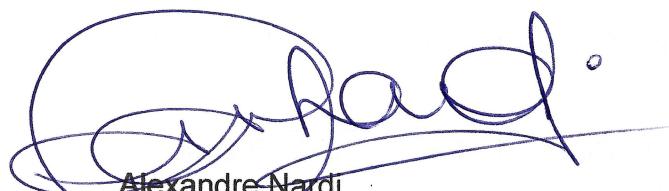


	290x160x50 mm for optics, sheath and trocar		
124.115	Baskets for optics with removable lid – 460x160x70 mm for optics, sheath and trocar	Class – I, Rule – I	07899524533155
124.116	Baskets for optics with removable lid – 460x160x70 mm for 1 endoscope	Class – I, Rule – I	07899524533537
124.121	Baskets for optics with removable lid – 290x80x50 mm for 2 optics	Class – I, Rule – I	07899524533391
124.122	Baskets for optics with removable lid – 460x80x50 mm for 2 optics	Class – I, Rule – I	07899524533117
124.131	Baskets for optics with removable lid – 540x250x70 mm for optics and cable	Class – I, Rule – I	07899524533124
124.141	Baskets for optics with removable lid – 640x150x70 mm for optics and cable	Class – I, Rule – I	07899524533148
124.211	Baskets for optics with removable lid – 290x80x50 mm for 1 optic	Class – I, Rule – I	07899524533100
124.212	Baskets for optics with removable lid – 460x80x50 mm without fixation system	Class – I, Rule – I	07899524533346
124.310	Baskets for robotic systems with removable lid – 690x90x100 mm for 1 scope (Xi/Si Endowrist/Single-site)	Class – I, Rule – I	07899524533179
124.312	Baskets for optics with removable lid – 540x250x70 mm for flexible scopes	Class – I, Rule – I	07899524533544
124.320	Baskets for robotic systems with removable lid - 560x50x70 mm for 1 optic (Xi)	Class – I, Rule – I	07899524533162
124.330	Baskets for robotic systems with removable lid – 690x260x100 mm for	Class – I, Rule – I	07899524533193

	6 scopes (Xi/Si Endowrist/Single-site)		
126.312	Baskets for optics with removable lid – 540x250x70 mm for flexible scopes	Class – I, Rule – I	07899524533544
134.117	Baskets with lid for small parts/pieces – 80x50x40 mm	Class – I, Rule – I	07899524533360
134.120	Baskets with lid for small parts/pieces – 80x80x40 mm	Class – I, Rule – I	07899524527192
134.133	Baskets with lid for small parts/pieces – 150x140x40 mm	Class – I, Rule – I	07899524532943
231.012	Tray – Ø 80x40 mm	Class – I, Rule – I	07898412948439
231.014	Tray – Ø 90x50 mm	Class – I, Rule – I	07898412948446
231.015	Tray – Ø 100x50 mm	Class – I, Rule – I	07898412949450
231.019	Tray – Ø 130x60 mm	Class – I, Rule – I	07898412949467
231.022	Tray – Ø 160x60 mm	Class – I, Rule – I	07898412949474
240.038	Tray – 260x120 mm	Class – I, Rule – I	07898412949825
662.510	Lids for baskets for reprocessing medical devices – 245x255 mm	Class – I, Rule – I	07899524503332
662.310	Lids for baskets for reprocessing medical devices – 405x255 mm	Class – I, Rule – I	07899524503233
662.210	Lids for baskets for reprocessing medical devices – 485x255 mm	Class – I, Rule – I	07899524503189
662.110	Lids for baskets for reprocessing medical devices – 540x255 mm	Class – I, Rule – I	07899524503134
662.130	Basket for reprocessing medical devices – 540x255x30 mm	Class – I, Rule – I	07899524503141
662.170	Basket for reprocessing medical devices – 540x255x70 mm	Class – I, Rule – I	07899524503165
662.190	Basket for reprocessing medical devices – 540x255x100 mm	Class – I, Rule – I	07899524503172
662.230	Basket for reprocessing medical devices – 485x255x30 mm	Class – I, Rule – I	07899524503196
662.270	Basket for reprocessing medical devices – 485x255x70 mm	Class – I, Rule – I	07899524503219

662.290	Basket for reprocessing medical devices – 485x255x100 mm	Class – I, Rule – I	07899524503226
662.330	Basket for reprocessing medical devices – 405x255x30 mm	Class – I, Rule – I	07899524503240
662.370	Basket for reprocessing medical devices – 405x255x70 mm	Class – I, Rule – I	07899524503264
662.390	Basket for reprocessing medical devices – 405x255x100 mm	Class – I, Rule – I	07899524503271
662.530	Basket for reprocessing medical devices – 245x255x30 mm	Class – I, Rule – I	07899524503349
662.570	Basket for reprocessing medical devices – 245x255x70 mm	Class – I, Rule – I	07899524503363
662.590	Basket for reprocessing medical devices – 245x255x100 mm	Class – I, Rule – I	07899524503370
662.650	Basket for reprocessing medical devices – 245x170x50 mm	Class – I, Rule – I	07899524503394
662.745	Basket for reprocessing medical devices – 265x120x45 mm	Class – I, Rule – I	07899524503400
665.905	Wire baskets for sterilization, storage and transport – 600x292x150 mm	Class – I, Rule – I	07899524532509
665.906	Wire baskets for sterilization, storage and transport – 600x292x260 mm	Class – I, Rule – I	07899524532516

Conformity assessment route: FAMI – Fábrica de Artefatos Metalúrgicos Itá Ltda. uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745: Class I: EU Declaration of conformity according to Annex IV + Annex V



Alexandre Nardi
CEO
São Caetano do Sul, 25/09/2024.

59.293.662/00001-40

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