



# FAMI UK Declaration of conformity

**Medical Devices Regulations 2002 Class I non-sterile, non-measuring devices**

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

**UK Responsible:** Easy Medical Device Limited  
 125 Deansgate  
 Manchester  
 M3 2LH  
 United Kingdom

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 UK Medical Devices Regulations 2002.

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 – 290x160x50 mm for optics, sheath and trocar	Class – I, Rule – I	07899524533186

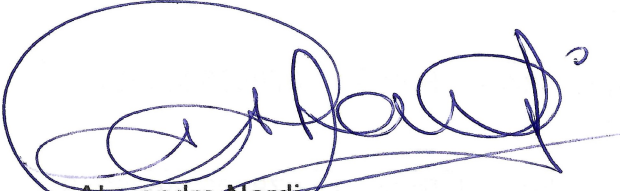


124.115	Baskets for optics with removable lid – 460x160x70 mm for optics, sheath and trocar	Class – I, Rule – I	07899524533155
124.116	Baskets for optics with removable lid – 460x160x70 mm for 1 endoscope	Class – I, Rule – I	07899524533537
124.121	Baskets for optics with removable lid – 290x80x50 mm 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 6 scopes (Xi/Si Endowrist/Single-site)	Class – I, Rule – I	07899524533193

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:** Annex VII – Self Certified



Alexandre Nardi  
CEO  
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59.293.662/00001-40

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