APPASAMY ASSOCIATES
Empowering Vision*

An EN ISO 13485:2016
Certified Company

GSTIN: 33AAAFA4543Q1ZE
PAN No. : AAAFA4543Q

Declaration of Conformity

Product: Ophthalmic Surgical Instruments (Micro Surgical Instruments)

Model(s): Surgical Knives, Surgical Cannulas, Needle Holders, Probing Needles / Manipulators, Scleral Depressors, Speculum, Scissors, Forceps, Hooks, Plugs, Retractors, Trephines, Lens Loop, Corneoscleral Punches, Curettes, Spoons, Needles, Lacrimal Instruments, Sterilization Containers, Associates Surgical Procedure kits.

Type Designation: Ophthalmic Surgical Instruments (Micro Surgical Instruments) supplied in non - sterile condition.

Conformity Assessment Route: Annex VII of MDD 93/42/EEC, as amended

Device Classification: Class I, Rule 6

GMDN Code:

Product Name	*GMDN code*	*Product Name*	*GMDN code*	*Product Name*	*GMDN code*
Surgical Knives	32764	Speculum	35349	Lens Loop	12319
Surgical Cannulas	17899	Scissors	46848	Corneoscleral Punches	13232
Needle Holders	12726	Forceps	62469	Curettes	32772
Probing Needles / Manipulators	13120	Hooks	32767	Spoons	35153
Scleral Depressors	42367	Plugs	46911	Needles	46549
Spatulas	32754	Retractors	35527	Lacrimal Instruments	13120
Spuds	16025	Trephines	14148	Sterilization Containers	13730
Associates Surgical Procedure kits	45149				

Contact Person: Mr. R. N. Kasthuri, Vice Chairman / CEO
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Registered Head Office Address	***Manufacturer Address:***	***European Representative:***
APPASAMY ASSOCIATES 20, SBI Officers' Colony, First Street, Arumbakkam, Chennai (Madras) – 600 106, Tamilnadu, India Phone: +91-44-32980153, 32980154 Fax: +91-44- 23630721, 23631208 Email: info@appasamy.com Website: www.appasamy.com	APPASAMY ASSOCIATES Address: SF No. 144/1 Navammal Kapper Village, M. N. Kuppam, Thennal (Post), Kandamangalam Taluk, Tamil Nadu 605102, INDIA Phone: +91 7695814612 Email: amsi.aa@gmail.com Website: www.appasamy.com	M/s Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands Phone: (31) (0) 70 345-8570, 70 346-7299 Fax: (31) (0) 70 346-7299 E-mail: europe@emergogroup.com Website: www.emergogroup.com

Appasamy Associates declares that the above-mentioned product(s) meet the provision of Council Directive 93/42/EEC, as amended and directive 2007/47/EC as transposed in the national laws of the Member states. The relevant documents and records are retained in Appasamy Associates premises.

1/6/18

QUALITY SYSTEM
M.N. KUPPAM

Manufacturing location :
SF. No. 144/1, Navammal Kapper Village,
M.N. Kuppam, Thennal Post, Kandamangalam (Taluk)
Villupuram Dist., Tamil Nadu, India - 605102.

Tel : (+91)-7695814612, 7695814613.
Email : mnk@appasamy.com
Web : www.appasamy.com.

For showing compliance to the essential requirements according to the council Directive MDD 93/42/EEC, as amended, we have referred the following harmonized standards;

#	Standard / Compliance	Publication Date	Title
1.	EN ISO 13485:2016 / AC:2016	25 Feb 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
2.	MDD 93/42/EEC, as amended by 2007/47/EC	Jun 1993	EC Directive on medical devices
3.	EN ISO 14971: 2012	30 Aug 2012	Medical Devices – Application of risk management to medical devices
4.	EN 1041: 2008	19 Feb 2009	Information supplied by the manufacturer of medical devices
5.	ISO 15223-1: 2016	Mar 2017	Symbols for use in the labeling of medical devices
6.	MEDDEV 2.7.1 Rev.4	2016	Clinical Evaluation: Guide for manufacturers and notified bodies
7.	MEDDEV 2.12-1 Rev 8	2013	Guidelines on a medical device vigilance system
8.	MEDDEV 2.5/5 Rev.3	1998	Translation procedure
9.	NB-MED/2.12/Rec1	2000	Post market surveillance (PMS)
10.	MEDDEV 2.12/2 rev 2	2012	Post Market Clinical Follow-up studies

Place: Tamil Nadu.

Date: June 1, 2018

Authorized Signatory

1/6/18

Name: Rajesh Candamourty
Designation: Management Representative

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CE

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