

ATTESTATION / CERTIFICATE / BESCHEINIGUNG n° 16708 rev. 5

Délivrée à Paris le 08 juin 2015

Issued in Paris on June 8th, 2015

Ausgestellt in Paris, den 08 Juni 2015

ATTESTATION CE / EC CERTIFICATE / EG-BESCHEINIGUNG

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

Genehmigung von dem vollständiges Qualitätssicherungssystem

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Anhang II, ohne den punkt 4, Richtlinie 93/42/EWG über Medizinprodukte

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer / Hersteller

MAILLEFER INSTRUMENTS HOLDING SARL

Chemin du Verger 3,

1338 BALLAIGUES SWITZERLAND

Catégorie du(des) dispositif(s) / Device(s) category / Produkt-Kategorie

Solution d'irrigation et de nettoyage canalaire, instruments dentaires, dispositifs d'obturation canalaire, pointes de papier stériles et non stériles. Moteurs et contre-angles.

Solution for irrigation and cleaning of root canals, dental instruments, products for root canal obturation, sterile and non sterile paperpoints. Endodontic micromotor and contra-angle.

Irrigations- und Reinigungslösung für Wurzelkanal, Dentalinstrumente, Produkte für Wurzelkanalfüllung, Sterile und nicht sterile Papierspitzen. Motoren und Winkelstücke.

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P129078, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P129078, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

LNE/G-MED bescheinigt, dass nach Überprüfung der im Prüfbericht n° P129078, enthaltenen Ergebnisse, das Qualitätssicherungssystem – für Designlenkung, Herstellung und Endkontrolle – der o.g. aufgeführten Medizinprodukte, den Anforderungen der Anhang II ohne den punkt 4 der Richtlinie 93/42/EWG entspricht..

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date / Gültig ab : July 9th, 2015 (included)

Valable jusqu'au / Expiry date / Gültig bis : July 8th, 2018 (included)



**On behalf of the Deputy Director
Cécile VAUGEYRADE
G-MED Certification Division Manager
der stellvertretende Direktor i.V.**

Identification des dispositifs / Identification of devices

Les produits couverts par ce certificat sont référencés sur la liste des produits (8 pages) authentifiée par le LNE/G-MED en date du 09 juillet 2015 / The products covered by this certificate are listed on the manufacturer's list of products (8 pages) authenticated by LNE/G-MED on July 9, 2015.

Identification des sites et activités / Identification of locations and activities

- Chemin du Verger, 3, 1338 BALLAIGUES, SUISSE :
Siège social, Responsable de la mise sur le marché / Headquarters, Legal manufacturer

LNE/G-MED

0459



On behalf of the Deputy Director
Cécile VAUGELADE
G-MED Certification Division Manager

Liste des produits couverts par l'attestation CE n°16708 rev.5

List of products covered by the EC Certificate n°16708 rev.5

Liste der produkte, welche mit dem EG Zertifikat n°16708 rev.5 abgedeckt werden

Item number	Product designation	Product class
A016602502000	THERMAFIL OBTURATORS	Class IIa
A016602502500	THERMAFIL OBTURATORS	Class IIa
A016602503000	THERMAFIL OBTURATORS	Class IIa
A016602503500	THERMAFIL OBTURATORS	Class IIa
A016602504000	THERMAFIL OBTURATORS	Class IIa
A016602504500	THERMAFIL OBTURATORS	Class IIa
A016602505000	THERMAFIL OBTURATORS	Class IIa
A016602505500	THERMAFIL OBTURATORS	Class IIa
A016602506000	THERMAFIL OBTURATORS	Class IIa
A016602507000	THERMAFIL OBTURATORS	Class IIa
A016602508000	THERMAFIL OBTURATORS	Class IIa
A016602509000	THERMAFIL OBTURATORS	Class IIa
A016602510000	THERMAFIL OBTURATORS	Class IIa
A016602511000	THERMAFIL OBTURATORS	Class IIa
A016602512000	THERMAFIL OBTURATORS	Class IIa
A016602513000	THERMAFIL OBTURATORS	Class IIa
A016602514000	THERMAFIL OBTURATORS	Class IIa
A016602590000	THERMAFIL OBTURATORS	Class IIa
A016700090000	THERMAFIL OBTURATORS Assorted Posterior Kit	Class IIa
A016800090000	THERMAFIL OBTURATORS Assorted Anterior Kit	Class IIa
A022C00001000	Gutta-Percha Points	Class IIa
A022C00001500	Gutta-Percha Points	Class IIa
A022C00002000	Gutta-Percha Points	Class IIa
A022C00002500	Gutta-Percha Points	Class IIa
A022C00003000	Gutta-Percha Points	Class IIa
A022C00003500	Gutta-Percha Points	Class IIa
A022C00004000	Gutta-Percha Points	Class IIa
A022C00004500	Gutta-Percha Points	Class IIa
A022C00005000	Gutta-Percha Points	Class IIa
A022C00005500	Gutta-Percha Points	Class IIa
A022C00006000	Gutta-Percha Points	Class IIa
A022C00007000	Gutta-Percha Points	Class IIa
A022C00008000	Gutta-Percha Points	Class IIa
A022C00009000	Gutta-Percha Points	Class IIa
A022C00010000	Gutta-Percha Points	Class IIa
A022C00011000	Gutta-Percha Points	Class IIa
A022C00012000	Gutta-Percha Points	Class IIa
A022C00013000	Gutta-Percha Points	Class IIa



Item number	Product designation	Product class
A022C00014000	Gutta-Percha Points	Class IIa
A022C00090000	Gutta-Percha Points	Class IIa
A022C00090100	Gutta-Percha Points	Class IIa
A022C00090200	Gutta-Percha Points	Class IIa
A022E00101000	Gutta-Percha Points	Class IIa
A022E00101500	Gutta-Percha Points	Class IIa
A022E00102000	Gutta-Percha Points	Class IIa
A022E00102500	Gutta-Percha Points	Class IIa
A022E00103000	Gutta-Percha Points	Class IIa
A022E00103500	Gutta-Percha Points	Class IIa
A022E00104000	Gutta-Percha Points	Class IIa
A022E00104500	Gutta-Percha Points	Class IIa
A022E00105000	Gutta-Percha Points	Class IIa
A022E00105500	Gutta-Percha Points	Class IIa
A022E00106000	Gutta-Percha Points	Class IIa
A022E00107000	Gutta-Percha Points	Class IIa
A022E00108000	Gutta-Percha Points	Class IIa
A022E00109000	Gutta-Percha Points	Class IIa
A022E00110000	Gutta-Percha Points	Class IIa
A022E00111000	Gutta-Percha Points	Class IIa
A022E00112000	Gutta-Percha Points	Class IIa
A022E00113000	Gutta-Percha Points	Class IIa
A022E00114000	Gutta-Percha Points	Class IIa
A022E00190000	Gutta-Percha Points	Class IIa
A022E00190100	Gutta-Percha Points	Class IIa
A022E00190200	Gutta-Percha Points	Class IIa
A022F00000100	Gutta-Percha Auxiliary Points	Class IIa
A022F00000200	Gutta-Percha Auxiliary Points	Class IIa
A022F00000300	Gutta-Percha Auxiliary Points	Class IIa
A022F00000400	Gutta-Percha Auxiliary Points	Class IIa
A022F00090000	Gutta-Percha Auxiliary Points	Class IIa
A022G00001000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00001500	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00002000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00002500	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00003000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00003500	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00004000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00004500	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00005000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00005500	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00006000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00007000	Gutta-Percha Points ISO Color-Coded	Class IIa

Item number	Product designation	Product class
A022G00008000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00009000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00010000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00011000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00012000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00013000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00014000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00090000	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00090100	Gutta-Percha Points ISO Color-Coded	Class IIa
A022G00090200	Gutta-Percha Points ISO Color-Coded	Class IIa
A022J00001500	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00002000	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00002500	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00003000	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00003500	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00004000	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00004500	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00006000	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00009000	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00090000	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022J00090100	Absorbent Paper Points ISO Color-Coded .04	Class IIa
A022K00001500	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022K00002000	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022K00002500	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022K00003000	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022K00003500	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022K00004000	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022K00090000	Absorbent Paper Points ISO Color-Coded .06	Class IIa
A022L00000100	Gutta-Percha Auxiliary Points	Class IIa
A022L00000200	Gutta-Percha Auxiliary Points	Class IIa
A022L00000300	Gutta-Percha Auxiliary Points	Class IIa
A022L00000400	Gutta-Percha Auxiliary Points	Class IIa
A022L00000500	Gutta-Percha Auxiliary Points	Class IIa
A022L00090000	Gutta-Percha Auxiliary Points	Class IIa
A022M00001500	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00002000	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00002500	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00003000	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00003500	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00004000	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00004500	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00006000	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00009000	Gutta-Percha Points ISO Color-Coded 4%	Class IIa

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Item number	Product designation	Product class
A022M00090000	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022M00090100	Gutta-Percha Points ISO Color-Coded 4%	Class IIa
A022N00001500	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022N00002000	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022N00002500	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022N00003000	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022N00003500	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022N00004000	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022N00090000	Gutta-Percha Points ISO Color-Coded 6%	Class IIa
A022O00000200	PROTAPER NEXT gutta-percha points	Class IIa
A022O00000300	PROTAPER NEXT gutta-percha points	Class IIa
A022O00090000	PROTAPER NEXT gutta-percha points	Class IIa
A022O00090100	PROTAPER NEXT gutta-percha points	Class IIa
A022Q00000200	PROTAPER NEXT paper points	Class IIa
A022Q00000300	PROTAPER NEXT paper points	Class IIa
A022Q00090000	PROTAPER NEXT paper points	Class IIa
A022Q00090100	PROTAPER NEXT paper points	Class IIa
A022R00001000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00001500	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00002000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00002500	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00003000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00003500	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00004000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00004500	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00005000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00005500	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00006000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00007000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00008000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00009000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00010000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00011000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00012000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00013000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00014000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00090000	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00090100	Absorbent Paper Points ISO Color-Coded	Class IIa
A022R00090200	Absorbent Paper Points ISO Color-Coded	Class IIa
A022T00001000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00001500	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00002000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00002500	Absorbent Paper Points .02 ISO Color-Coded	Class IIa

Item number	Product designation	Product class
A022T00003000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00003500	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00004000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00004500	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00005000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00005500	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00006000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00007000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00008000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00009000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00010000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00011000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00012000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00013000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00014000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00090000	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00090100	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022T00090200	Absorbent Paper Points .02 ISO Color-Coded	Class IIa
A022W00010100	PROTAPER UNIVERSAL PAPER POINTS	Class IIa
A022W00010200	PROTAPER UNIVERSAL PAPER POINTS	Class IIa
A022W00010300	PROTAPER UNIVERSAL PAPER POINTS	Class IIa
A022W00090100	PROTAPER UNIVERSAL PAPER POINTS	Class IIa
A022W00090200	PROTAPER UNIVERSAL PAPER POINTS	Class IIa
A022X00010100	PROTAPER UNIVERSAL GUTTA-PERCHA POINTS	Class IIa
A022X00010200	PROTAPER UNIVERSAL GUTTA-PERCHA POINTS	Class IIa
A022X00010300	PROTAPER UNIVERSAL GUTTA-PERCHA POINTS	Class IIa
A022X00090100	PROTAPER UNIVERSAL GUTTA-PERCHA POINTS	Class IIa
A022X00090200	PROTAPER UNIVERSAL GUTTA-PERCHA POINTS	Class IIa
A023Y00000400	GT series X Gutta-Percha-Points	Class IIa
A023Y00000600	GT series X Gutta-Percha-Points	Class IIa
A023Y00000800	GT series X Gutta-Percha-Points	Class IIa
A023Y00090000	GT series X Gutta-Percha-Points	Class IIa
A023Z00000400	GT series X Paper Points	Class IIa
A023Z00000600	GT series X Paper Points	Class IIa
A023Z00000800	GT series X Paper Points	Class IIa
A023Z00090000	GT series X Paper Points	Class IIa
A024W00000L01	PAPER POINTS FOR WAVEONE	Class IIa
A024W00000P01	PAPER POINTS FOR WAVEONE	Class IIa
A024W00000S01	PAPER POINTS FOR WAVEONE	Class IIa
A024W00090001	PAPER POINTS FOR WAVEONE	Class IIa
A024X00000L00	WAVEONE gutta percha points	Class IIa
A024X00000P00	WAVEONE gutta percha points	Class IIa
A024X00000S00	WAVEONE gutta percha points	Class IIa

Item number	Product designation	Product class
A024X00090000	WAVEONE gutta percha points	Class IIa
A034802502000	THERMAFIL OBTURATORS	Class IIa
A034802502500	THERMAFIL OBTURATORS	Class IIa
A034802503000	THERMAFIL OBTURATORS	Class IIa
A034802503500	THERMAFIL OBTURATORS	Class IIa
A034802504000	THERMAFIL OBTURATORS	Class IIa
A043522101200	System GT Accessory Files	Class IIa
A043522501200	System GT Accessory Files	Class IIa
A045022101200	System GT Accessory Files	Class IIa
A045022501200	System GT Accessory Files	Class IIa
A045100001200	System GT Obturators Accessory	Class IIa
A047022101200	System GT Accessory Files	Class IIa
A047022501200	System GT Accessory Files	Class IIa
A048522101200	System GT Accessory Files	Class IIa
A048522501200	System GT Accessory Files	Class IIa
A048600001200	System GT Obturators Accessory	Class IIa
A052100000400	GT Series X Obturator	Class IIa
A052100000600	GT Series X Obturator	Class IIa
A053100000400	GT Series X Obturator	Class IIa
A053100000600	GT Series X Obturator	Class IIa
A053100000800	GT Series X Obturator	Class IIa
A054100000400	GT Series X Obturator	Class IIa
A054100000600	GT Series X Obturator	Class IIa
A054100000800	GT Series X Obturator	Class IIa
A062000000100	ProUltra	Class IIa
A062000000200	ProUltra	Class IIa
A062000000300	ProUltra	Class IIa
A062000000400	ProUltra	Class IIa
A062000000500	ProUltra	Class IIa
A062000090000	ProUltra	Class IIa
A062100000600	ProUltra	Class IIa
A062100000700	ProUltra	Class IIa
A062100000800	ProUltra	Class IIa
A062100090000	ProUltra	Class IIa
A063000000100	ProUltra	Class IIa
A063000000200	ProUltra	Class IIa
A063000000300	ProUltra	Class IIa
A063000000400	ProUltra	Class IIa
A063000000500	ProUltra	Class IIa
A063000090000	ProUltra	Class IIa
A063100000600	ProUltra	Class IIa
A063100000700	ProUltra	Class IIa
A063100000800	ProUltra	Class IIa

Item number	Product designation	Product class
A063100090000	ProUltra	Class IIa
A064000000100	ProUltra	Class IIa
A064000000200	ProUltra	Class IIa
A064000000300	ProUltra	Class IIa
A064000000400	ProUltra	Class IIa
A064000000500	ProUltra	Class IIa
A064000000600	ProUltra	Class IIa
A064000090000	ProUltra	Class IIa
A065000000100	ProUltra	Class IIa
A065000000200	ProUltra	Class IIa
A065000000300	ProUltra	Class IIa
A065000000400	ProUltra	Class IIa
A065000000500	ProUltra	Class IIa
A065000000600	ProUltra	Class IIa
A065000090000	ProUltra	Class IIa
A090100000000	GLYDE File Prep syringe kit	Class IIa
A090200000000	GLYDE File Prep Intro Package	Class IIa
A090300000000	GLYDE File Prep Syringe Tips	Class IIa
A090500000000	GLYDEdoses pack	Class IIa
A103200000200	X-SMART PLUS	Class IIa
A103200000300	X-SMART PLUS	Class IIa
A141100010100	Protaper Universal Obturator	Class IIa
A141100010200	Protaper Universal Obturator	Class IIa
A141100010300	Protaper Universal Obturator	Class IIa
A141100010400	Protaper Universal Obturator	Class IIa
A141100010500	Protaper Universal Obturator	Class IIa
A141100011100	Protaper Universal Obturator	Class IIa
A141100011200	Protaper Universal Obturator	Class IIa
A141100011300	Protaper Universal Obturator	Class IIa
A141100011400	Protaper Universal Obturator	Class IIa
A141100011500	Protaper Universal Obturator	Class IIa
A170000010L00	WAVEONE obturators	Class IIa
A170000010P00	WAVEONE obturators	Class IIa
A170000010S00	WAVEONE obturators	Class IIa
A170000011L00	WAVEONE obturators	Class IIa
A170000011P00	WAVEONE obturators	Class IIa
A170000011S00	WAVEONE obturators	Class IIa

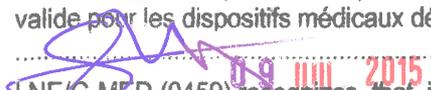
Ballaigues, 08 May 2015

MAILLEFER INSTRUMENTS
HOLDING S.à.R.L.




Luc Etienne
Management Representative

LNE/G-MED (0459) reconnaît que son certificat CE est
valide pour les dispositifs médicaux décrits


LNE/G-MED (0459) recognizes that its EC certificate
is valid for the medical devices listed