

**EC DECLARATION OF CONFORMITY
DECLARATION CE DE CONFORMITE
EG-KONFORMITÄTSERKLÄRUNG**

Nous,

We,

Wir,

**E.M.S. Electro Medical Systems S.A.,
Chemin de la Vuarpillière 31,
1260 Nyon, Switzerland**déclarons sous notre seule
responsabilité que les références du
produit :declare under our sole responsibility
that the references of the product :erklären in alleiniger Verantwortung,
daß die Referenzen des Produkts:**LASER Fibers**de satisfont aux dispositions
applicables des directives relatives aux
dispositifs médicaux 93/42/CEE &
2007/47/CEE, Annexe II (Système
complet d'assurance de qualité), hors
point (4),are conforming to the relevant
provisions of the Medical Device
Directives 93/42/EEC &
2007/47/EEC, Annex II (Full quality
assurance system), excluding
section (4),den einschlägigen Bestimmungen
der richtlinien 93/42/EWG &
2007/47/EWG Medizinprodukte,
Anhang II (Vollständiges
Qualitätssicherungssystem), ausser
Nummer (4), entsprechen,**sous le numéro de certificat CE :****Under the EC Certificate No. :**
50081-16-09**EG Zertifikat-Nr. :****Date de la dernière recertification :****Date of last recertification :**
2020-06-15**Datum der letzten Rezertifizierung:****Nom, adresse et numéro
d'identification de l'organisme notifié:****Name, address and identification
number of Notified Body:**
DEKRA Certification GmbH
Handwerkstrasse 15,
70565 Stuttgart, Germany **CE**₀₁₂₄**Name, Adresse und Kenn-
nummer der Benannten Stelle:**La documentation technique est
disponible auprès d'E.M.S. Electro
Medical Systems S.A.Technical documentation is kept
available by E.M.S. Electro Medical
Systems S.A.Die technische Dokumentation wird
durch E.M.S. Electro Medical
Systems S.A. gehalten.**Nom et adresse du Mandataire:****Name and address of the
Authorized Representative:****Name und anschrift des
Bevollmächtigter:**E.M.S. Electro Medical Systems FRANCE SARL
32, Route de Pontarlier
39460 Foncine-Le-Haut – France**Lieu, date****Place, date**
Nyon, 2021-05-25
Valid until : 2024-05-26**Ort, Datum****Fonction, nom et signature****Function, name and signature****Funktion, Name und Unterschrift**

Marketing Manager, Urology

Jérôme Blondeau

Head of Quality

Timothée Deblock

References of all classes except class I, are compliant with Annex II (Full Quality Assurance System), excluding section (4):



References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
FR-276#	SET	SmartFibers Power 272µm 10x reusable / 5 parts	Ila	7	N/A
FR-275#	SET	SmartFibers Power 200µm 10x reusable / 5 parts	Ila	7	N/A
FR-273#	SET	SmartFibers Power 272µm single use 5 parts	Ila	7	N/A
FR-272#	SET	SmartFibers Power 200µm single use 5 parts	Ila	7	N/A
FR-186#	SET	SmartFibers 272µm 10x reusable / 5 parts	Ila	7	N/A
FR-185#	SET	SmartFibers 272µm single use 5 parts	Ila	7	N/A
FR-182#	SET	SmartFibers 550µm 10x reusable / 5 parts	Ila	7	N/A
FR-181#	SET	SmartFibers 550µm single use 5 parts	Ila	7	N/A
FR-180#	SET	SmartFibers 365µm 10x reusable / 5 parts	Ila	7	N/A
FR-179#	SET	SmartFibers 365µm single use 5 parts	Ila	7	N/A
FR-178#	SET	SmartFibers 200µm 10x reusable / 5 parts	Ila	7	N/A
FR-177#	SET	SmartFibers 200µm single use 5 parts	Ila	7	N/A
FR-348#	SET	Box SmartFibers 1'000µm single use / 5 parts	Ila	7	2021-05-25
FR-349#	SET	Box SmartFibers 1'000µm 10x reusable / 5 parts	Ila	7	2021-05-25
FR-350#	SET	Box SmartFibers 800µm single use / 5 parts	Ila	7	2021-05-25
FR-351#	SET	Box SmartFibers 800µm 10x reusable / 5 parts	Ila	7	2021-05-25
FR-352#	SET	Box SmartFibers 150µm single use / 5 parts	Ila	7	2021-05-25
FR-354#	SET	Box SmartFibers 800µm 5x reusable / 5 parts	Ila	7	2021-05-25
FR-353#	SET	Box SmartFibers 1'000µm 5x reusable / 5 parts	Ila	7	2021-05-25
FR-358#	SET	Box SmartFibers 200µm 5x reusable / 5 parts	Ila	7	2021-05-25
FR-357#	SET	Box SmartFibers 272µm 5x reusable / 5 parts	Ila	7	2021-05-25
FR-356#	SET	Box SmartFibers 365µm 5x reusable / 5 parts	Ila	7	2021-05-25
FR-355#	SET	Box SmartFibers 550µm 5x reusable / 5 parts	Ila	7	2021-05-25

Note: the # symbol indicates that the product is available as a configurable item with various combinations of optional items.