

MEDI MARK ® EUROPE	QUALITY ASSURANCE MANUAL <i>Annex Management declaration</i>	Ref: MQ Annex Management declaration 13/01/2020
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Management declaration

« Authorized Representative means the natural or legal person established in the Community who, being explicitly designated by the Manufacturer, acts and may be addressed by Authorities and Bodies in the Community in substitution for the Manufacturer with regard to the latter's obligation ».

MediMark® Europe was the first European Company of Regulatory Affairs which has set up, in 1995, the standards of Authorized Representative's activities, and is, since 1998, certified to ISO 9001, in order to provide services in continuation with the quality system requirements of his Customers.

It is the policy of MediMark® Europe to provide its Customers the highest quality of services for meeting customer/MME contractual provisions and requirements from the EU regulations and National Competent Authorities (NCA) regarding the CE Marking of medical devices.

Our Quality System covers the following processes as European Authorized Representative:

- Management Process
- Contract Process
- Technical Process (Technical File, Product notification, Vigilance)
- On-line regulatory assistance
- Financial Business management

The objectives of this quality management system are:

- To continually improve the services provided by updating permanently its awareness of European Regulatory Affairs through a regular review of the European legislation and direct contacts with NCAs of the European Economic Area.
- To continually improve the processes by which the services are supplied with the commitment to be in compliance with the legal and EU regulatory requirements.

Periodic Management Review Meetings include establishment and review of the achievement of the company quality objectives. During a meeting, the Management Declaration is reviewed for continuing suitability.

A copy of this Declaration is made available to all staff members via the computer system

Grenoble, January 13th, 2020

René CLEMENT
President- C.E.O., MediMark Europe SARL

