



Organisme belge d'Accréditation  
Belgische Accreditatieinstelling  
Belgische Akkreditierungsstelle  
Belgian Accreditation Body

EA MLA Signatory

Annexe au certificat d'accréditation  
Bijlage bij accreditatiecertificaat  
Annex to the accreditation certificate  
Beilage zur Akkreditierungszertifikat

# 084-QMS

EN ISO/IEC 17021-1:2015

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**Maureen Logghe**

La Présidente du Bureau d'Accréditation

Voorzitster van het Accreditatiebureau

Chair of the Accreditation Board

Vorsitzende des Akkreditierungsbüro

**De accreditatie werd uitgereikt aan / L'accréditation est délivrée à  
The accreditation is granted to / Die akkreditierung wurde erteilt für:**

**APRAGAZ ASBL  
Chaussée de Vilvorde 156  
1120 Bruxelles**

**PED**

Directive 2014/68/EU du 15 mai 2014 relative aux équipements sous pression  
Richtlijn 2014/68/EU van 15 mei 2014 betreffende drukapparatuur

**MED**

Directive 2014/90/UE du 23 juillet 2014 relative aux équipements marins  
Richtlijn 2014/90/CE van 23 juli 2014 betreffende marine uitrusting

<b>1. Certification of quality management systems within the framework of the European directives and linked to a notification</b>		
<b>Product</b>	<b>Conformity assessment procedure</b>	<b>Annexes or articles of the directives</b>
<b>1.1. PED-directive 2014/68/EU</b>		
Pressure equipment as referenced in PED-directive	Conformity to type based on quality assurance of the production process	Annex III - Module D
	Quality assurance of the production process	Annex III - Module D1
	Conformity to type based on pressure equipment quality assurance	Annex III - Module E
	Quality assurance of final pressure equipment inspection and testing	Annex III - Module E1
	Conformity based on full quality assurance	Annex III - module H
	Conformity based on full quality assurance plus design examination	Annex III - Module H1
<b>1.2. MED Directive 2014/90/EU</b>		
Fire protection Portable and mobile fire extinguishers	Production quality assurance	art 15. annex II, module D
	Product quality assurance	art 15. annex II, module E

2. Certificatie van kwaliteitsmanagement systemen / Certification de systèmes de management de la qualité / Certification of quality management systems				
Toepassing / Application / Application: NBN EN ISO 9001: 2015				
	Secteur Sector Sector	Description	Beschrijving	Description
Technical cluster	EAC	ISO 9001		
Chemicals	12	Industrie chimique non comprise l'industrie pharmaceutique	Chemische producten met uitzondering van de farmaceutische nijverheid	Chemicals, chemical products and fibres
Mechanical	17	Métallurgie et travail des métaux	Metalen in primaire vorm en producten van metaal	Basic metals and fabricated metal products
	18	Fabrication de machines et équipements non classés ailleurs	Machines, apparaten en werktuigen	Machinery and equipment
	19	Fabrication d'équipements électriques et électroniques	Elektrische en optische apparaten en instrumenten	Electrical and optical equipment
	22	Fabrication de matériels de transport autres que navals et aérospatiaux	Fabricatie van transportmiddelen andere dan schepen en lucht- en ruimtevaartuigen	Other transport equipment
Transport & Waste management	31	Transport, entreposage et communication	Vervoer, opslag en communicatie	Transport, storage and communication
	39	Services collectifs, sociaux et personnels non classés ailleurs	Overige gemeenschapsvoorzieningen en sociaal-culturele en persoonlijke diensten	Other social services
Services	35	Services fournis principalement aux entreprises autres que l'ingénierie	Overige zakelijke dienstverlening met uitzondering van engineering	Other services

<b>3. Certificatie van Medische hulpmiddelen / Certification de produits relative aux dispositifs médicaux / Certification of Medical devices</b>		
<b>3.1. Certificatie van management systemen overeenkomstig ISO 13485:2016/ certification de systèmes de mangement suivant ISO 13485:2016 / certification of management systems according to ISO 13485:2016</b>		
Technische Domeinen Domaines Techniques Technical Areas	Wettelijke fabrikanten Fabricants Légaux Legal Manufacturers	Bedrijven die aanverwante diensten leveren (bv. onderaannemers, distributie, transport, ...) Sociétés fournissant des services ancillaires (p.e. sous-traitants, distribution, transport,...) Companies providing associated services (e.g. subcontractors, distribution, transportation, ...)
<b>3.1.1 - NON-ACTIVE MEDICAL DEVICES</b>		
General non-active, non-implantable medical devices ( limitations to: Non-active devices for injection, infusion, transfusion and dialysis, Non-active medical devices with measuring function, Non active instruments)	X	X
Non-active dental devices and accessories	X	X
<b>3.1.2 - ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES</b>		
General active medical devices (limitations to : devices for extra-corporal circulation, infusion and haemopheresis, Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia, Active surgical devices, Active dental devices, Active devices for disinfection and sterilization, Active devices for patient positioning and transport, Software, Medical gas supply systems and parts thereof)	X	X

Devices for radiation therapy and thermo therapy (including: Devices utilising non-ionizing radiation)	X	X
Active (non-implantable) medical devices other than specified above		X
<b>3.1.3 - STERILIZATION METHODS FOR MEDICAL DEVICES</b>		
Ethylene oxide gas sterilization (EOG)	X	X
Moist heat	X	X
Aseptic processing	X	X
Radiation sterilization (e.g. gamma, x-ray, electron beam)		X
Sterilization method other than specified above		X