AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
II.2. Eticheta (etichete) dispozitivului medical şi al ambalajului	Eticheta_1L
I.3. Certificatul CE	Certificat CE
II.3. Instrucţiunile de utilizare	Instructiuni de utilizare
II.2. Eticheta (etichete) dispozitivului medical şi al ambalajului	Eticheta_5L
II.2. Eticheta (etichete) dispozitivului medical şi al ambalajului	Sticker
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producator	Reprezentant
DM000021787	DETERGENT TRI-ENZIMATIC PENTRU INSTRUMENTAR MEDICAL	ANIOSYME XL3	1 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000021788	DETERGENT TRI-ENZIMATIC PENTRU INSTRUMENTAR MEDICAL	ANIOSYME XL3	5 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000019356	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	SURFANIOS PREMIUM	LICHID, 1 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000019357	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	SURFANIOS PREMIUM	LICHID, 5 L		Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000021789	DEZINFECTANT DE NIVEL ÎNALT PENTRU STERILIZARE LA RECE	ANIOXIDE 1000	5 L, ACTIVATOR	1081.299	Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000017744	DEZINFECTANT DE NIVEL ÎNALT PENTRU STERILIZARE LA RECE	STERANIOS 20% CONCENTRAT	5 L	182000	Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000017743	DEZINFECTANT DE NIVEL ÎNALT PENTRU STERILIZARE LA RECE	STERANIOS 20% CONCENTRAT	500 ML	182000	Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000017737	DEZINFECTANT PENTRU STERILIZAREA LA RECE A DISPOZITIVELOR MEDICALE	ANIOSEPT ACTIV	PRAF, 5 KG	1896	Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000021766	DEZINFECTANT PENTRU DISPOZITIVE MEDICALE NON-INVAZIVE	ANIOSPRAY QUICK	1 L	2084.073	Franta	LABORATOIRES ANIOS	ERICON S.R.L.
DM000017739	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR	ANIOSYME SYNERGY 5	1 L	2235000	Franta	LABORATOIRES ANIOS	ERICON S.R.L.

Digitally signed by Bunic Gheorghe
Date: 2021.01.11 21:27:10 EET
Reason: MoldSign Signature
Location: Moldova

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* / CERTIFICADO **n° 31390 rev. 13**
Délivrée à Paris le 20 novembre 2019
Issued in Paris on November 20th, 2019
Establecido en Paris, el 20 noviembre 2019

ATTESTATION CE / *EC CERTIFICATE* / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
Aprobación del sistema completo de Seguro de la calidad
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
ANEXO II excluyendo el punto 4 Directiva 93/42/CEE relativa a los productos sanitarios
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* / Fabricante

LABORATOIRES ANIOS
1 rue de l'Espoir
59260 LEZENNES FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category* / Categoría del producto

Détergents désinfectants ou désinfectants pour DM invasifs et/ou non invasifs

Detergent disinfectant or disinfectant for invasive and/or non invasive devices

Detergentes desinfectantes o desinfectantes para DM invasivos y/o no invasivos

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177315, 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.

GMED certifies that, on the basis of the results contained in the file referenced P177315, 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.

GMED certifica que después del examen de los resultados indicados en el expediente P177315, el sistema de calidad para el diseño, la fabricación y el control final - de los productos sanitarios enunciados anteriormente - cumple con los requisitos del anexo II excluyendo el punto 4 de la Directiva 93/42/CEE.

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* / Fecha efectiva : **November 20th, 2019 (included)**

Valable jusqu'au / *Expiry date* / Fecha de expiración :**June 10th, 2021 (included)**

GMED SAS GMED SAS
GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3_ESP-F-V0-07-2018

GMED - 31390 rev. 13
Modifie le certificat 31390-12

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
CERTIFICADO
N° 26638 rev. 5

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by
GMED certifica que el sistema de gestión de la calidad adoptado por

LABORATOIRES ANIOS
1 rue de l'Espoir
59260 LEZENNES FRANCE

pour les activités */ for the activities* / para las actividades
Conception, développement, fabrication, prestations associées et vente de produits antimicrobiens, détergents et matériels pour procédés de désinfection de dispositifs médicaux dédiés aux hôpitaux et cliniques.

Design, development, manufacturing, servicing and sales of antimicrobial products, detergents and materials for disinfecting processes of medical devices dedicated to hospitals and clinical sectors.

Diseño, desarrollo, fabricación, servicios y venta de productos antimicrobianos, detergentes y materiales para los procesos de desinfección de dispositivos médicos dedicados a hospitales y clínicas.

réalisées sur le(s) site(s) de */ performed on the location(s)* / que se realizan en
LABORATOIRES ANIOS
1 rue de l'Espoir 59260 LEZENNES FRA
LABORATOIRES ANIOS
3330 rue de Lille 59262 SAINGHIN-EN-MELANTOIS FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards
es conforme a las exigencias de las normas internacionales

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité */ Effective* / Fecha efectiva **November 21st, 2019 (included)**
Valable jusqu'au */ Expiry date* / Fecha de expiración **June 10th, 2021 (included)**
Etabli le */ Issued on/* Fecha de preparación **November 21st, 2019**

GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_SQ_ESP-F-V0-07-

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 26638–5
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 26638-4

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Medical Device Disinfectants according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	002201 MR2
Certificate unique ID	170750848
Effective date	2019-09-09
Expiry date	2024-05-26
Frankfurt am Main	2019-09-09

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

CERTIFICATE

This is to certify that the company

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and delivery of disinfectants for medical devices.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2016

Certificate registration no.	002201 MP2016
Certificate unique ID	170709071
Effective date	2018-06-25
Expiry date	2021-06-24
Frankfurt am Main	2018-06-25

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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