



Sänger GmbH

Industriegebiet Herdwiesen
Zeller Weg 30
74575 Schrozberg / Germany
Tel. (0 79 35) 72 24 - 0
Fax (0 79 35) 72 24 199
E-Mail: info@sanger.de
<http://www.sanger.de>

Postanschrift/Postal address:
Postfach 140
74573 Schrozberg
Germany

E-Mail
j.fessel@sanger.de

Sänger GmbH - Postfach 140 - 74573 Schrozberg

ECOCHIME Ltd.
Attn. Mr. Ion
5/1, Cuza Voda str.
2060MD, Chisinau
REPUBLIC OF MOLDOVA

Ihr Zeichen, Ihre Nachricht vom

Unser Zeichen, unsere Nachricht vom
Jf/lm/#Kdkorrau/20150316

Telefon
07935-7224-241

Name
Julia Fessel

Datum
16.03.2015

Declaration

We, company Sänger GmbH, hereby declare that company Ecochime Ltd is an authorized distributor for company Sänger GmbH for the Moldavian market.

Best regards,
Sänger GmbH

Julia Fessel

Julia Fessel



Certificate

Production Quality Assurance System Approval Annex V of the Directive on Medical Devices

ECM, Bismarckstr.106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex V of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Sänger GmbH

**Industriegebiet Herdwiesen / Zeller Weg 30
74575 Schrozberg, Germany**

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by Annex V, section 4.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number

364-17-117

Registered under

Z/17/04144E

Valid until

December 3rd, 2022

Aachen, December 4th, 2017


Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zig.de
ZLG-BS-240.10.12

Annex I to Certificate Z/17/04144E

Number of Pages: 1 of 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Gloves, Surgical	11-883
Single use devices	Gloves, Examination/Treatment	11-882

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.



¹ UMDNS Code is optional

Annex I to Certificate Z/12/02905

Date of revision: August 28th, 2013

Number of Pages: 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Disinfectant for non-invasive medical devices	/
Single use devices	Gloves, Surgical	11-883
Single use devices	Gloves, Examination/Treatment	11-882
Single use devices	Casework, General Purpose (procedure pack, §10, Sect. 3)	15-896
Single use devices	Covers	15-571

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.



¹ UMDNS Code is optional

CERTIFICATE

DIN EN ISO 9001



PÜG Prüf- und Überwachungsgesellschaft mbH
herewith certifies that the company



Certificate holder:

Sänger GmbH
Zeller Weg 30, 74575 Schrozberg
Germany

Scope:

Manufacture and distribution of medical products,
trading and distribution of protective equipment,
hand disinfectants, spa products and other
commodities for household and industry

introduced a quality system in accordance with DIN EN ISO 9001:2015 and uses this effectively.

The evidence has been provided within the framework of the certification audit.

This certificate is valid from: **2021-09-23**
until: **2024-09-22**

Audit report no: **20092021_K13736**

Certificate registration no. **K13736-20210922-Q-en**



Gäufelden, 2021-09-22



Manager of Certification Authority
Health care

This is the translation of the original German certificate. For legal reasons, the original German certificate is valid.

CERTIFICATE

DIN EN ISO 13485



PÜG Prüf- und Überwachungsgesellschaft mbH
herewith certifies that the company



Certificate holder:

Sänger GmbH
Zeller Weg 30, 74575 Schrozberg
Germany

Scope:

Manufacture and distribution of non-sterile
disposable examination gloves.
Trading with medical products.

introduced a quality system in accordance with DIN EN ISO 13485:2016 and uses this effectively.

The evidence has been provided within the framework of the certification audit.

This certificate is valid from: **2021-09-23**
until: **2024-09-22**

Audit report no: **20092021_K13736**

Certificate registration no. **K13736-20210922-D-en**



Gäufelden, 2021-09-22


Manager of Certification Authority
Health care

This is the translation of the original German certificate. For legal reasons, the original German certificate is valid.