

CERTIFICATE



CERTIFIED



Certificate of Assessment

Kyoto Kagaku Co., Ltd.

15 Kitanechoya-cho Fushimi-ku Kyoto-shi Kyoto, Japan

EQA's certification is hereby granted to the above company's
Management System conforming to the standard and scope below

ISO 9001:2015 & JIS Q 9001:2015
ISO 14001:2015 & JIS Q 14001:2015

Scope

**Developing, Manufacturing and Distribution of Skill Training Products
for Medical and Nurse Training**
Developing, Manufacturing and Distribution of Medical Imaging Phantoms

Registration No. QA210095, EA210096

First issued on 4 June 2021

Re-issued on 24 May 2024

This certificate is valid from 24 May 2024 to 3 June 2027

Appendix for multiple sites is QA210095a, EA210096a.



The Chief Executive

Further clarifications regarding the scope of this certificate and the applicability
of requirements may be obtained by consulting EQA
The certificate written in the local language is the original
#903, 9F, 50, Digital-ro 33-gil, Guro-gu, Seoul, Korea, 08377
URL: www.eqaworld.com

IA 07311

Appendix



Certificate of Assessment

Registration Number : QA210095, EA210096

Organization Name : Kyoto Kagaku Co., Ltd.

Address of Head office : 15 Kitanechoya-cho Fushimi-ku Kyoto-shi Kyoto, Japan

The Subjects of This Certificate Includes the sites below.

Tokyo Branch :

2F NREG Hongo 3 chome Bldg., 3-26-6 Hongo Bunkyo-ku Tokyo, Japan

Sendai Office :

6F Taiyoseimei Sendaihoncho Bldg., 3-4-18 Honcho Aoba-ku Sendai-shi Miyagi, Japan

[Scope]

Distribution of Skill Training Products for Medical and Nurse Training

Distribution of Medical Imaging Phantoms

(QMS : Sales, Inspection, Improvement)

EMS : Operational control, Performance, Improvement)

Registration No. QA210095a, EA210096a

First issued on 4 June 2021

Re-issued on 24 May 2024

This certificate is valid from 24 May 2024 to 3 June 2027

This is an appendix for certificate of registration No. QA210095, EA210096.



CERTIFIED



The Chief Executive

Further clarifications regarding the scope of this certificate and the applicability of requirements may be obtained by consulting EQA

The certificate written in the local language is the original

#903, 9F, 50, Digital-ro 33-gil, Guro-gu, Seoul, Korea, 08377
URL: www.eqaworld.com

IA 07312

To whom it may concern

28 April 2025

NON – CE DECLARATION

Declaration Issued by:

Commercial name: **Kyoto Kagaku Co., Limited**

Registered address: 15 Kitanekeoya-cho, Fushimi-ku, Kyoto, 612-8388, Japan

As the producer of the products:

- 11381-100 MW2A Male Catheterization/Enema simulator
- 11433-000 MW52 Female Catheterization/Enema simulator II
- 11442-000 MW60 Tracheostomy Simulator

Description and function designation of the product:

Simulators and Phantoms for Training and Simulation in Healthcare.

We declare that the said products do not belong to the group of medical devices in sense of directive 93/42/EEC. The products are safe under the conditions of common use in compliance with the user manual and meet the requirements of hygienic safety.

Name: Masahiro Wasa, General Manager

Kyoto Kagaku Europe GmbH

Duly authorized to sign

 **KYOTO KAGAKU**
Europe GmbH

De-Saint-Exupery-Str.10, 60549 Frankfurt, Germany
TEL: +49 (0) 69 506028 160

To whom it may concern

28 April 2025

Certificate of Origin

Statement Issued by:

Commercial name: **Kyoto Kagaku Co., Limited**

Registered address: 15 Kitanekeya-cho, Fushimi-ku, Kyoto, 612-8388, Japan

As the producer of the products:

- 11351-000 Arterial Puncture Training Wrist Light tone
- 11390-999 Difficult Airway Management Simulator Assessment System
- 11381-100 MW2A Male Catheterization/Enema simulator
- 11433-000 MW52 Female Catheterization/Enema simulator II
- 11442-000 MW60 Tracheostomy Simulator

Description and function designation of the product:

Simulators and Phantoms for Training and Simulation in Healthcare.

We hereby declare that our medical simulators are being produced in Japan under high quality standards.

Only "KYOTO KAGAKU CO., LTD" has the patented technology and exclusive know-how to make aforementioned simulators, phantoms and parts.

Name: Masahiro Wasa, General Manager

Kyoto Kagaku Europe GmbH

Duly authorized to sign

 **KYOTO KAGAKU**
Europe GmbH
De-Saint-Exupery-Str.10. 60549 Frankfurt, Germany
TEL: +49 (0) 69 506028 160

To whom it may concern

28 April 2025

Letter of Authorization

We "**KYOTO KAGAKU CO., LTD**" with our principal office and manufacturing facility at 15 Kitaneckoya-cho Fushimi-ku Kyoto 612-8388, Japan, hereby confirm and certify that **S.C. IMUNOTEHNOMED S.R.L.**, located at MD-2028 Chisinau, 42, Gh. Asachi, str., Republic of Moldova is authorized to do the following:

- quote and supply Kyoto Kagaku goods
- conclude contracts
- demonstrate & install equipment
- give professional support
- provide after sales service, during and after the warranty period

to State University of Medicine and Pharmacy "Nicolae Testemițanu", specifically through the tender 21388616.

KYOTO KAGAKU Europe GmbH

Name Masahiro Wasa

Title Kyoto Kagaku Europe GmbH General Manager

Signature

 **KYOTO KAGAKU**
Europe GmbH
De-Saint-Exupery-Str.10. 60549 Frankfurt, Germany
TEL: +49 (0) 69 506028 160