# CERTIFICATE

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We herewith certify that

#### Mr. Dumitrescu Honoriu

took part in the training for one Bausch + Ströbel high-speed ampoule sterilizing and filling line from 26 - 30 March 2021.

The line is comprising of the following machines:

- Sterilizing tunnel type DHT 2550
- Ampoule filling and sealing machine type AFV 8010
- Laminar flow unit type LFO 9060

The machines of this line are equipped with Siemens Programmable Logic Control - PLC and SÜTRON control panel (with foil-covered keyboard and clear text indication)

#### **OBJECTIVES OF TRAINING:**

- Operation of the machines without supervision
- Change-over of size parts (different ampoule sizes - 1ml, 2ml, 5ml and 10 ml)
- Errors have been simulated and remedied and all machine functions as well as the control panel have been tested, etc.
- Fault recovery for the machines

BAUSCH+STRÖBEL

Postfach 20 · D-74530 lishofen

(07904) 701-0 · ☑ 74894

FAX (07904) 701-222

Ilshofen, 30 March 2021

BAUSCH + S TRÖBEL Maschinenfabrik Ilshofe n GmbH + Co.

i.V.

Otto Feil (//

i. A.

Andreas Plank

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# CLEANROOM TESTING AND CERTIFICATION BOARD – INTERNATIONAL





# **DUMITRESCU HONORIU**

has participated in practical training and passed theoretical examinations in

## **CLEANROOM TESTING**

Level attained: Associate

Chris Delaney

Secretary CTCB-I

Koos Agricola

Chairperson CTCB-I

Certificate No.IE003

Date of issue: November 2021

# Certificate



#### Mr. Honoriu Pavel Dumitrescu

has completed a four day ECA GMP Education Course from 9 - 12 December 2021 in Copenhagen, Denmark covering the following subject

### **Pharmaceutical Engineering**

Contents of the Course:

An Overview – How Engineering impacts on GMP and the Regulatory Area
Overview – The important Documents in the Pharmaceutical Industry
SOP- Requirements and Basic Rules of Writing
FDA-Compliant Design of Vessels, Piping, Valves and Gaskets
Hygienic Design Principles and Practical Examples
Qualification and Validation, Risk Analysis, URS/FDS, DQ, FAT/SAT
IQ,OQ,PQ – Requalification, Process Optimization, Process Validation, Cleaning Validation
GMP-compliant Management, Calibration in Pharmaceutical Production Processes
Change Control/Deviations, Audit Change Control/Deviations, Audit Workshops: Documentation - SOP, GMP-conform Design, Qualification

Heidelberg, 12 December 2021

Signature of Course Leader

In co-operation with

