EMERGO EUROPE
Quality Assurance & Regulatory Affairs

CE Registration Certificate

This is to certify that, in accordance with the In Vitro Diagnostic Medical Device Directive 98/79/EC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

ERMA Inc.
2-31-6 Yushima, Bunkyo-ku
Tokyo, 113-0034
Japan

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received the In Vitro Diagnostic Medical Device Registrations on the following dates:

21 September 2007
See attached product listing

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the In Vitro Diagnostic Medical Devices fulfill the applicable requirements of Directive 98/79/EC.

25 September 2007

Digitally signed by Ceaicovschi Tudor
Date: 2022.12.23 10:31:16 EET
Reason: MoldSign Signature
Location: Moldova

Rene van de Zande
President & CEO
Emergo Europe

EMERGO EUROPE
Quality Assurance & Regulatory Affairs

Annex A to the Emergo Europe CE Registration Certificate

dated 25 September 2007

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
PCE-210	23 01 10 01	Other (Self-Certify)	21 September 2007
PCE-210N	23 01 10 01	Other (Self-Certify)	21 September 2007

Certificate JP06/040143

The management system of

ERMA INC.

3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

This certificate is valid from 16 November 2021 until 16 November 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 10. Certified since 16 November 2006

Authorised by

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