

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

DFI Co., Ltd.
388-25 Gomo-ro, Jillye-myeon
Gimhae-si, Gyeongsangnam-do 50875
Republic of Korea

has established and applies a quality management system for medical devices
for the following scope:

See attachment(s) for the scope

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-11-08
Certificate Registration No.: SX 60144149 0001
An audit was performed. Report No.: 12031518 002
This Certificate is valid until: 2022-11-05

Certification Body



Date 2019-11-08


M.Sc. M. Aihara

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60144149 0001
Report No.: 12031518 002

Organization: DFI Co., Ltd.
388-25 Gomo-ro, Jillye-myeon
Gimhae-si, Gyeongsangnam-do 50875
Republic of Korea

Scope:

Design and Development, Manufacture and Distribution of
In Vitro Diagnostic-Urine Strips and analyser, Salivary and
vaginal pH test strip, Quality control solution, Cardiac
Markers, Fertility Tests, Pregnancy Tests, Infection Markers
Tumor Markers and Blood monitoring systems



Certification Body

Date: 2019-11-08


M.Sc. M. Aihara