

GIẤY CHỨNG NHẬN ISO 13485:2016

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 08 tháng 09 năm 2022

Người đại diện hợp pháp của cơ sở

Xác nhận bằng chữ ký số

GIÁM ĐỐC

Uông Tuấn Phương

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

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

**Design and development, manufacture, distribution and
servicing of instruments and reagents for
clinical diagnostic
(see attachment for sites included)**

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: 2020-01-08
Certificate Registration No.: SX 60145545 0001
An audit was performed. Report No.: 28300434 004

This Certificate is valid until: 2022-12-12

Certification Body



Date 2020-01-08

A blue ink signature is written over a circular stamp. The stamp contains the text "TÜV Rheinland LGA Products GmbH" around the perimeter and "TÜV Rheinland Zertifizierungsstelle" in the center. The signature is written in a cursive style.

D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60145545 0001
Report No.: 28300434 004

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope:

Site included:

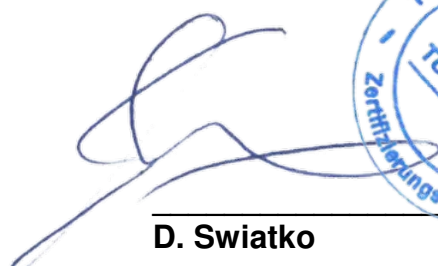

Polígono Industrial Can Tapioles
Naves 7, 12 y 13
08110 Montcada i Reixac
Spain

Activity: Labelling and assembling of reagents,
warehousing and shipment of instruments
and reagents for clinical diagnostic

Certification Body



Date: 2020-01-08



D. Swiatko

The bottom right section contains a handwritten signature in blue ink over a horizontal line. To the right of the signature is a circular blue seal. The seal features a central logo consisting of a triangle with a smaller triangle inside it, and the text "TÜV Rheinland LGA Products GmbH" around the perimeter. The word "Zertifizierungsstelle" is written vertically on the left side of the seal.