

Title	ISO 13485 Self declaration BIOSYS USA	Document no.	Rev.
		DF-141-E	3



SELF DECLARATION for QMS

BIOSYS USA LLC
444 Brickell Ave, Suite 700
Miami, FL 33131

has introduced and applies a
Quality Management System

for the scope

**development and sales of
image analyzers for Multiwell plates**

which is based on the requirements of the following standard

EN ISO 13485

Medical devices - Quality management systems -
Requirements for regulatory purposes

EN ISO 13485:2016 +AC:2018+A11:2021 - ISO 13485:2016

BIOSYS USA LLC applies all rules and guidelines which are also applied at BIOSYS Scientific
Devices GmbH, Kiefernweg 10, 61184 Karben, Germany.

BIOSYS Scientific Devices GmbH was audited and certified by

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ce.de>

The mdc audit at BIOSYS Scientific Devices GmbH has proven that their Quality Management
System meets all requirements of the standard mentioned above.

BIOSYS Scientific Devices GmbH certificate details:

Valid from	2023-01-12
Valid until	2025-08-14
Registration no.	D1499700002
Report no.	P23-00029-256601
Berlin	2023-01-11

Werner Freber

Signature General Manager

03/15/2023

Date