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, production and sales of
image analyzers for Multiwell plates (incl. in vitro diagnostics)

which meets all 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 the same 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 audit has proven that the applied Quality Management System does meet all requirements of the standard mentioned above. BIOSYS Scientific Devices GmbH certificate details:

Valid from	2025-08-15	Registration No.	D1499700004
Valid until	2028-08-14	Report No.	P25-00533-331980

Signature General Manager

September 1st, 2025
Date