BIOSYS Scientific Devices GmbH, Kiefernweg 10, 61184 Karben/Germany
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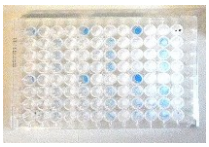
Declaration in reference to IVD

BIOSYS Scientific® devices are used to apply image processing technology to evaluate assays in Multiwell, Microtiter and Microfilter plates in the field of research as well as routine and diagnostic work.

The Bioreader®7000, EazyReader® 7000 and Biocount® 7000 are general laboratory instruments and they do not have to be registered as IVD medical devices because they only count objects once the assay has been completed and they are not part of the actual biochemistry of the assays.[1]

Picture 1: Bioreader® 7000, EazyReader® 7000 and Biocount® 7000 units



Picture 2: Typical Microfilter plate for the Elispot assay

Further declaration refers especially to the **Elispot** kits **T-Spot®** from Revvity[3] and **T-Track®** from Mikrogen[4]:

- In connection with these applications all BIOSYS Scientific® devices present well images of 96 well Microfilter plates with a PC plus monitor and submit count results. These results represent reactive T-cells by use of the Elispot assay. Therefore they are used for assisting the evaluation by the operator.[5]
- The Bioreader® 7000 -E was verified with TB Elispot reference plates from a reference laboratory.[6] Additionally, enough publications and collaborative studies had been performed which ensure the accuracy and comparability of the Elispot evaluation by use of the Bioreader®.

  Nevertheless, it is necessary to verify any BIOSYS Scientific® device on-site by use of the samples of the laboratory as differences in sample preparation and automation lead to different characteristics of the spots.

  The counts need to be evaluated, corrected (if needed) and finally approved by a qualified medical technician.[5]
- The usage of BIOSYS Scientific® devices are only permitted by laboratory personnel who were trained by a medical product consultant and authorized by BIOSYS Scientific®.
- BIOSYS Scientific® devices are semi-automatic. The operator makes the final decision of the diagnosis.[5]

[1] However, all of these BIOSYS Scientific® devices meet the applicable requirements of EU 2017/746 IVD-R ‚In-Vitro Diagnostics' as well as further standards / requirements / guidelines described on next page.
[3] Company Revvity Ltd. (formerly Oxford Immunotec), 143 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4SE, U.K.
[4] Company Mikrogen GmbH, Anna-Sigmund-Str. 10, 82061 Neuried, Germany.
[5] This is published in the Instruction-Of-Use (IFU) of the kit manufacturer Revvity and Mikrogen.
[6] The related clinical performance study was done with T-Spot®.TB reference plates and the Bioreader® 7000 -E alpha (SN: 356).

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The pioneer in versatile bioanalytical multiwell plate analyzing

The manufacturer BIOSYS Scientific Devices GmbH hereby declares that the Bioreader® 7000, EazyReader® 7000 and Biocount® 7000 meet the following **EU and ISO product standards (incl. standards for IVD product class A):**

Standards	**Date**	**Description**
ISO 12100	2010	Safety of Machines (For the User)
DIN EN 61010-1	2020-03	Safety Regulations for electrical measuring-, control- and laboratory Equipment – Part 1: General Requirement
DIN EN 61010-2-101	2017-10	Safety Regulations for electrical measuring, control and laboratory Equipment – Part 2-101; Special Requirement for in vitro diagnostics (IVD) medical Devices
DIN EN 61326-1	2018	Electrical measurement, control and laboratory Equipment EMC Requirement-Medical in vitro Part 1: General Requirement
DIN EN 61326-2-6	2018	Electrical measurement, control and laboratory Equipment EMC Requirement. Part 2-6: Particular Requirement - -In vitro diagnostic medical Equipment (IVD)
IEC 61000-3-2 To -4		Electrical interference Resistance

as well as following **EU and ISO system standards:**

DIN EN ISO 18113-3 :2021 EN ISO 15223-1:2020	2021	In vitro diagnostic medical Devices – Provision of Information by the manufacturer – Part 3: Apparatus for in vitro diagnostic examination for use by qualified Staff. (EN ISO 15223-1:2020 Symbols)
EN ISO 14971:2019	2019	Medical Devices – Application of Risk Management to Medical Devices Relevant publications: Appendix 2
ISO 13485:2016/2021	2021	Medical Devices – Quality Management Systems –Requirements for regulatory purposes
ISO 20916:2019	2019	In vitro diagnostic medical devices – Clinical performance studies on human test material – Good practice (See Annex 2 publications [TD-306-D]
EN 62304:2006 + A1:2015	2015	Medical Device Software - Software Lifecycle Processes. Based partly on GAMP 4 (SDS and Lifecycle).
EN 62366-1:2015	2015	Medical Devices - Part 1: Application of suitability for use of medical Devices. Applied and improved as far as relevant.
GAMP 4	2007	The documentation according to the GAMP 4 specifications has been practiced since 2007.

The person responsible for compliance with regulatory requirements: Werner Freber (Dipl.-Ing.), Kiefernweg 10, 61184 Karben, Germany.

Further technical documentation sees: TD-306-D deliverable information from manufacturer.

DF-13-E-7	Title: Declaration in reference to IVD
Changed : 15th May 2024 Anthony Fry	Checked/Released: 20th June 2024 Werner Freber