Certificate of Verification

MDSS GmbH hereby declares

that an Authorized Representative's Mandate according to the

EU Regulation 2017/746 (IVDR) is in place and that the following tasks have been carried out

in accordance with the requirements of the IVDR on behalf of the Manufacturer:

Arena BioScien

Block 5, Street 9 inside the Ismalia Free Zone

41511 Ismailia

EGYPT

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51, at the disposal of competent authorities for the period referred to in Article 10(7);

MDSS complied with the registration obligations laid down in Article 113.3(f) and until Eudamed is fully functional, the corresponding provisions of Directives 98/79/EC has been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2023-11-29
(YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 718568

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the IVDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	Notified device name(s)	EDMA Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
TF-06, Rev.01	BioScien – Blood Culture Media	Blood Culture Adult Blood Culture Pediatric Blood Culture Neonate	14.01.11.01	A	Arena BioScien Declaration of Conformity Signed 28/10/2023	N.A.	N.A.	DE/CA09/00090441
	BioScien – Bacteriology – Powder Media	Blood Base Agar Brain Heart Infusion Agar Brain Heart Infusion Broth Cled Agar MacConkey Agar Muller Hinton Agar Nutrient Agar Nutrient Broth Sabaroued Agar S.S. Agar Triple Sugar Agar Alkaline Peptone water Chocolate Agar Base Columbia Agar Base Kligler Iron Agar Mannitol Salt Agar Phenol Red Lactose Broth Plate Count Agar Potato Dextrose Agar Simmons Citrate Agar Sulfur Indole Motility Medium Tryptic Soya Agar Tryptic Soy broth LB-Agar Eosine Methylene Blue (EMB) Agar Cetrimide Agar GC Agar Fluid Thioglycollate Medium Lysine Iron Agar (LIA) Hektoen Enteric Agar Egg Yolk Agar	14.01.01.03					DE/CA09/00090442

	BioScien – Transport Media	MIO Medium (Motility Indole Ornithine Medium) PPLO Agar Dextrose Peptone Agar Sabouraud Dextrose Broth Urea Agar Base XLD Agar TCBS Agar Selenite F Broth MacConkey Agar without Crystal Violet YEAST STARCH GLUCOSE AGAR Cary-Blair Transport Medium Viral Transport Media (Inactivated or Non-inactivated)	14.01.01.03 14.01.02.20					DE/CA09/00118010

*The registration number has been issued by the German Competent Authority.