



Anaerobe Systems
THE OXYGEN-FREE SPECIALISTS
A BIOLOG BRAND



Declaration of Conformity – Anaerobic Culture Media

Date of Issue: July 21, 2025

Manufacturer: SRN: US-MF-000040030
Anaerobe Systems
15906 Concord Circle
Morgan Hill, CA 95037 USA

EU Authorized Representative: SRN: NL-AR-000037688
Casus Europe B.V.
3511 BK Utrecht
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Product Group, Codes: Anaerobic Culture Media
Refer to page 2 for variants included in group.

Basic UDI-DI: 081004890ANAEROBEDT
Classification: Class A, Rule 5 (a)
Notified Body: Not applicable, IVD device self-certified
Certification: EN ISO 13485:2016 RN: SX2233872-1 TUV Rheinland Exp.2027-07-11

Intended Purpose: TruePRAS™ Anaerobic Culture Media is intended for the transport, preservation, or cultivation of a wide variety of microorganisms from specimens to aid in the isolation of bacteria for in vitro diagnostic and / or research / general laboratory purposes.

Intended Users: Scientists, laboratory, and healthcare professionals trained in anaerobic microbiology techniques working in areas such as clinical, research, industrial, pharmaceutical and veterinary applications.

We, as the manufacturer of the device, take sole responsibility for and hereby declare the above mentioned product meets the provisions of Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.

Conformity Assessment Route: Annex I, II, III

Place of issue: Morgan Hill, CA 95037 USA

Signature:

Signed by:

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Authorized Signatory:

Steve Cox
VP of Operations - Morgan Hill



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Appendix A

ANAEROBIC CULTURE MEDIA

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PLATE MEDIA					
Catalog #	ITEM DESCRIPTION	EMDN	Class	UDI-DI	GMDN
AS-111	PRAS BRU	W0104010405	Class A	00810048900008	58688
AS-141	PRA BRU (4 plates /pkg)	W0104010405	Class A	00810048900015	58688
AS-614	PRAS BRUCELLA (150mm)	W0104010405	Class A	00810048900336	58688
AS-112	PRAS LKV	W0104010405	Class A	00810048900022	58585
AS-142	PRAS LKV (4 plates /pkg)	W0104010405	Class A	00810048900039	58585
AS-113	PRAS PEA	W0104010405	Class A	00810048900060	58585
AS-143	PRAS PEA (4 plates /pkg)	W0104010405	Class A	00810048900077	58585
AS-114	PRAS BBE	W0104010405	Class A	00810048900046	58585
AS-144	PRAS BBE (4 plates /pkg)	W0104010405	Class A	00810048900053	58585
AS-303	PRAS BRU LKV PEA (3 plates /pkg)	W0104010405	Class A	00810048901302	62106
AS-444	PRAS BRU PEA LKV BBE (4 plates /pkg)	W0104010405	Class A	00810048901333	62106
AS-213	PRAS CCFA	W0104010405	Class A	00810048900121	58585
AS-228	PRAS TSA-T (2 plates /pkg)	W0104010405	Class A	00810048900183	58685
AS-229	PRAS YMEA (2 plates /pkg)	W0104010405	Class A	00810048900190	58685
AS-511	PRAS EYA	W0104010405	Class A	00810048900206	58585
AS-646	PRAS CDC (4 plates /pkg)	W0104010405	Class A	00810048900428	58688
	PLATE MEDIA Bi-plate (non-chromogenic media only)	EMDN	Class	UDI-DI	GMDN
Catalog #	ITEM DESCRIPTION	EMDN	Class	UDI-DI	GMDN
AS-322	PRAS BRU, BBE/PEA (2 plates /pkg)	W0104010405	Class A	00810048901319	62106
AS-212	PRAS BBE/LKV	W0104010405	Class A	00810048900107	62106
AS-242	PRAS BBE/LKV (4 plates /pkg)	W0104010405	Class A	00810048900114	62106
AS-302	PRAS BRU, BBE/LKV (2 plates /pkg)	W0104010405	Class A	00810048901296	62106
AS-323	PRAS BRU, PEA, BBE/LKV (3 plates /pkg)	W0104010405	Class A	00810048901326	62106
TRANSPORT MEDIA					
Catalog #	ITEM DESCRIPTION	EMDN	Class	UDI-DI	GMDN
AS-911	PRAS ANAEROBIC TRANSPORT MEDIUM (ATM)	W0104010203	Class A	00810048901241	63232
AS-914	PRAS ANAEROBIC TRANSPORT MEDIUM SURGERY PK	W0104010203	Class A	00810048901258	63232
AS-915	PRAS ANAEROBIC TISSUE TRANSPORT MEDIUM SURGERY PK (ATTM-SP)	W0104010203	Class A	00810048901425	63232



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AS-919	PRAS ANAEROBIC TISSUE TRANSPORT MEDIUM (ATTM)	W0104010203	Class A	00810048901272	63232
AS-920	PRAS DENTAL TRANSPORT MEDIUM (DTM)	W0104010203	Class A	00810048901265	63232
TUBED MEDIA					
Catalog #	ITEM DESCRIPTION	EMDN	Class	UDI-DI	GMDN
AS-872	PRAS BHI BROTH (5mL)	W0104010206	Class A	00810048901104	58687
AS-105	PRAS BRU BROTH (4mL)	W0104010206	Class A	00810048900084	58586
AS-811	PRAS CHOPPED MEAT (7mL)	W0104010206	Class A	00810048900619	58687
AS-823	PRAS CHOPPED MEAT CARBOHYDRATE (7mL)	W0104010206	Class A	00810048900633	58687
AS-813	PRAS CHOPPED MEAT GLUCODE (7mL)	W0104010206	Class A	00810048900626	58687
AS-822	PRAS PY GLUCOSE (mL)	W0104010206	Class A	00810048900725	58586
AS-805	PRAS THIOGLYCOLATE BROTH (5mL)	W0104010206	Class A	00810048900596	58586
AS-801	PRAS THIOGLYCOLATE MEDIUM (7mL)	W0104010206	Class A	00810048900589	58586

Rev0: 07/21/2025 Initial issue.

Rev1: 07/24/2025 AS-911, 914, 915, 919, 920 Transport Mediums changed to GMDN 63232 from GMDN 33355 (obsolete).