

EU Declaration of Conformity

Name of Device / Product Group	Conditions (AB, AG, AN, CD, CN, HP)
Group Description	Products for the generation of specific optimal atmospheric conditions for micro-organisms
Product Code / Product and Trade Name	See attached product schedule
 Legal Manufacturer	Oxoid Limited Wade Road, Basingstoke, Hampshire, RG24 8PW, UK SRN: GB-MF-000016914
 European Authorized Representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, NL SRN: NL-AR-000013157
Risk Class	Class A in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/746 (IVDR) Class A in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/746 (IVDR)
Conformity Assessment Procedure Performed	Self-declared in accordance with Articles 17 and 48(10) of Regulation (EU) 2017/746 (IVDR)
Certificate(s) Issued	EN ISO 13485:2016 – MD 80930

We, as the legal manufacturer of the device(s) take sole responsibility for and hereby declare that the listed product(s) meet the provisions of the following regulation:

- Regulation (EU) 2017/746 on *in vitro* Diagnostic Medical Devices (IVDR)

Signature:

Name:

Function: Regulatory Affairs

Issued in: United Kingdom

Effective Date: Refer to electronic signature



Product Schedule

The products related to MBD-BT-DOC-0020 Rev 6 - IVDR DOC Oxoid Ltd Class A (Conditions) are listed below:

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384AnaerobicJarW8	AB0025A	ANAEROBOX 2.5L	AnaeroBox™ 2.5L Box with Lid and Seal (AB0025A) is an accessory intended to be used to maintain optimal atmospheric conditions for cultured microorganisms, e.g., microaerophilic, enriched CO ₂ and anaerobic conditions.	5032384491322	43520	0083
	AB0025L	ANAEROBOX 2.5L LID		5032384500017		
	AB0025S	ANAEROBOX 2.5L SEAL		5032384500024		
	AB0035A	ANAEROBOX 3.5L	AnaeroBox™ 3.5L Box with Lid and Seal (AB0035A) is an accessory intended to be used to maintain optimal atmospheric conditions for cultured microorganisms, e.g., microaerophilic, enriched CO ₂ and anaerobic conditions.	5032384520930		
	AB0035L	ANAEROBOX 3.5L LID		5032384552818		
	AB0035S	ANAEROBOX 3.5L SEAL		5032384552658		

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384PlasticPouchesVY	AG0020C	PLASTIC POUCHES	Compact Plastic Pouch (AG0020C) is an accessory intended to be used to maintain optimal atmospheric conditions for cultured microorganisms e.g., microaerophilic, enriched CO ₂ and anaerobic conditions.	5032384034925	43520	0223
5032384AnaerobicJarW8	AG0025A	ANAEROJAR 2.5L	AnaeroJar™ 2.5L (AG0025A) is an accessory intended to be used to maintain optimal atmospheric conditions for cultured microorganisms, e.g., microaerophilic, enriched CO ₂ and anaerobic conditions.	5032384027804	43520	0083
	AG0026A	ANAEROJAR 2.5L BASE		5032384029600		
	AG0027A	ANAEROJAR 2.5L LID		5032384027811		
	AG0028A	ANAEROJAR 2.5L HANDLE		5032384029617		
	AG0029A	ANAEROJAR PLATE CARRIER		5032384027828		
	AG0030A	ANAEROJAR 2.5L O RING		5032384027835		
	AG0031A	ANAEROJAR 2.5L CLIPS		5032384036219		
5032384PlasticPouchesVY	AG0060C	W-ZIP PLASTIC POUCHES	W-Zip Seal Pouch (AG0060C) is an accessory intended to be used to maintain optimal atmospheric conditions for cultured microorganisms e.g., microaerophilic, enriched CO ₂ and anaerobic conditions.	5032384131259	43520	0223

Product Schedule

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5032384SealingClips7R	AN0005C	SEALING CLIPS FOR ANAEROGEN COMPACT	Compact Sealing Clip (AN0005C) is an accessory intended to be used to maintain optimal atmospheric conditions for cultured microorganisms e.g., microaerophilic, enriched CO2 and anaerobic conditions.	5032384029938	43520	0223
5032384AnaerogenCompactSV	AN0010C	ANAEROGEN COMPACT 10 PACK	The Thermo Scientific™ Oxoid™ AnaeroGen™ (AN0010C, AN0020C, AN0010W, AN0020D, AN0025A, AN0035A) are accessories intended to be used with the other accessories part of the AnaeroGen™ products range, for the generation of optimal atmospheric conditions for the growth of anaerobic microorganisms.	5032384029921	43520	0469
	AN0010W	ANAEROGEN W-ZIP COMPACT		5032384161935		
	AN0020C	ANAEROGEN COMPACT 20 PACK		5032384069132		
	AN0020D	ANAEROGEN COMPACT 10 PACK		5032384446148		
	AN0025A	ANAEROGEN 2.5L 10 PACK		5032384028665		
	AN0035A	ANAEROGEN 3.5L 10 PACK		5032384028672		

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384CO2GenLN	CD0020C	CO2GEN COMPACT (20 PER PACK)	The Thermo Scientific™ Oxoid™ CO2Gen™ Compact Sachet (CD0020C) and the Thermo Scientific™ Oxoid™ CO2Gen™ Sachet (CD0025A) are accessories intended to be used with the other accessories part of the AnaeroGen™ products range, for the generation of optimal atmospheric conditions for microorganisms requiring an enriched carbon dioxide atmosphere.	5032384123261	43520	0185
	CD0025A	CO2GEN (10 SACHETS PER PACK)		5032384034932		

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
5032384CampygenCL	CN0020C	CAMPYGEN COMPACT	The Thermo Scientific™ Oxoid™ CampyGen™ (CN0020C, CN0025A and CN0035A) are accessories intended to be used with the other accessories part of the AnaeroGen™ products range, for the generation of optimal atmospheric conditions for the growth of microaerophilic microorganisms.	5032384034611	43520	0164
	CN0025A	CAMPYGEN (2.5 LITRES)		5032384028870		
	CN0035A	CAMPYGEN (3.5 LITRES)		5032384028887		

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5032384DiscEjectorsSU	HP0053A	SINGLE DISC EJECTORS	The Thermo Scientific™ Oxoid™ Antimicrobial Susceptibility Individual Disc Dispenser (HP0053A), provided in a pack of six individual disc dispensers, is used as an accessory to the AST disc range for clinical and non-clinical use. The Thermo Scientific™ Oxoid™ Antimicrobial Susceptibility Individual Disc Dispenser (HP0053A) accurately applies discs onto the media of choice with a simple, self-tamping, one-handed operation.	5032384028405	43520	0505
5032384CartridgeCont93	HP0055A	DESICCATED CARTRIDGE CONTAINER	The Thermo Fisher™ Oxoid™ Cartridge Container with Desiccant (HP0055A) is a cartridge storage container complete with desiccant as an accessory to the Antimicrobial Susceptibility Testing range for clinical and non-clinical use. It is intended to safely store opened cartridges protecting them from moisture.	5032384060122	43520	0470

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