

CE Declaration of Conformity

We,

Atlas Medical

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Declare our responsibility that the following product:

Stain kits For Histology & Microbiology:

Carbol Fuchsin (Gram) Stain	Field Stain (Solution B) stain
Carbol Fuchsin (Ziehl-Neelsen)Stain	Giemsa Stain
Crystal Violet (for Gram Stain) Stain	Gram's Iodine
Eosin Y (1% Aqueous) Stain	Gram's Decolouriser
Eosin Y (5% Aqueous) Stain	Haematoxylin Harris Stain
Eosin Y (1% Alcoholic) Stain	Leishman Stain
Field Stain (Solution A) stain	Lugol's Iodine
Malachite Green stain	May Grunwald Stain
Methylene Blue stain	Papanicolaou Stain
Safranin O Stain	Wright's Stain
ZN Decolouriser	

Is produced under Atlas quality system (ISO9001: 2008) and (ISO13485: 2003) supported by Lloyd's certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN 18113-1, -2 :2011, EN ISO 15223:2012

EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999,

EN ISO 13612:2002, EN ISO 13641:2002

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer

Atlas Medical

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Cambridge, CB4 0WX, UK

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	October- 2004	22.10.2015		