

EU Declaration of Conformity

In accordance with ISO EN IEC 17050-1:2010

Document Ref: AMI-VZF-EDC-002/en Rev 005 Dated 11 Oct 2021



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EU AUTHORISED REPRESENTATIVE

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Amity Group, trading as Amity International, Amity Healthcare EU Ltd and Amity Ltd, declares that the declaration covers:

the **Amzyme range** of medical devices described at ANNEX A
and forming part of the Amity Viruzyme Product Family.

The Products have been classified as Class I (Annex IX Rule 1) and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC and is subject to the procedure set out in Annex VII of Directive 93/42/EEC as amended by Directive 2007/47/EC.

The above products are in conformity with the following standards:

Subject	Standard Applied
Medical Devices -QMS	EN ISO 13485:2016
Symbols & Labelling	EN 15223:2021
Information supplied	EN 1041:2008+A1:2013



Thereby meeting the essential requirements of the following Directives/
Regulations:
Directive (93/42/EEC (Medical Devices Regulation) – as amended
Directive (EC) 1907/2006 (REACH Regulation)

Year in which the CE Mark was first affixed: 2015

I hereby declare that the products named above have been designed and manufactured to comply with the relevant sections of the above referenced standards and meets all essential requirements of the specified Directives/Regulations.

Signed: Mr Ram Singh
Position Technical Director
Amity Ltd
Location Barnsley, England

Signature 

Date: 11 Oct 2021

**Infection
Controlled**

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ANNEX A
AMZYME Range

The Amzyme Products as listed at Table 1 below:

TABLE 1 Amzyme Product Range								
Basic UDI-DI: 506072225AAA0003JN								
DEVICE PURPOSE: Enzymatic Cleaning of medical devices, Device Class (EU) I								
Product Name	Product Form	Unit Size	Pack Size If available	Part Number Reference	GMDN No	EU CODE	Product UDI-DI G-TIN 13	Product UDI-DI G-TIN 14
Amzyme 3	Concentrate	1L	10 x 1L	J48A	38773		5060722251574	15060722251571
		5L	4 x 5L	J48B	38773		5060722251598	15060522251595
		25L	N/A	J48C	38773		5060722252182	-----
Amzyme 3 Manual	Concentrate	1L	10 x 1L	J48AM	38773		5060722252182	15060522252189
		5L	4 x 5L	J48BM	38773		5060722251604	15060522251601
		25L	N/A	J48CM	38773		5060722251628	-----