

We

Name + address + Single Registration Number of manufacturer:	Laboratoires Anios 1 rue de l'Espoir 59260 Lezennes France FR-MF-000011756
Name + address + Single Registration Number of authorized representative:	Not Applicable

declare on our sole responsibility that

the medical device	ANIOSYME SYNERGY 5
Type / Intended Use	DETERGENT INVASIVE / 5 enzyme cleaning product for instrumentation
Class	I
Rule according to MDR Annex VIII	Rule 1

Meets all the provisions of the Regulation (EU) 2017/745 on medical devices.

Notified body name, address, ID	Not Applicable
Conformity assessment procedure	MDR (EU) 2017/745 article 52, Annex II and III
ID of the certificates issued	Not Applicable
Common Specifications	Not Applicable
Validity	31 December 2028

Valid in conjunction with the batch related release documentation

Sainghin 05/06/2024	 Digitally signed by Pouravi Krefting Date: 2024.06.05 10:32:52 +02'00'
Place, date	Pouravi Krefting Name and function (Person Responsible for Regulatory Compliance)

Signed on behalf of: **Laboratoires Anios**



TECHNICAL FILE - EU DECLARATION OF CONFORMITY
(MDR)

Réf : FQ279C
Date : 24/04/24

Medical Device	Brand	Device Subcategory	Packaging variant	Basic UDI-DI
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	005 1x200L	359761LA0150C1LIME
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	015 2x5L	359761LA0150C1LIME
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	018 1x25L	359761LA0150C1LIME
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	024 1x10L	359761LA0150C1LIME
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	036B 4x5L	359761LA0150C1LIME
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	038 2x5L	359761LA0150C1LIME
ANIOSYME SYNERGY 5	ANIOS	<i>Detergent invasive</i>	095B 12x1L	359761LA0150C1LIME