

TECHNICAL FILE - EU DECLARATION OF CONFORMITY (MDR)

Réf : FQ279B Date : 21/07/22

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	ANIOS RL		
Type / Intended Use	RINSING AGENT INVASIVE / Rinse aid for instrumentation		
Class	1		
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	26 May 2024	

Valid in conjunction with the batch related release documentation

Sainghin 09/01/2023		Sainghin 09/01/2023	
	Dieter Wirbals		Jean-Noël Bertho
Place, date	Name and function (Person Responsible for Regulatory Compliance)	Place, date	Name and function (RD,E Representative)

Signed on behalf of: Laboratoires Anios



TECHNICAL FILE - EU DECLARATION OF CONFORMITY (MDR)

Réf : FQ279B Date : 21/07/22

Medical Device	Brand	Device Subcategory	Packaging variant	Basic UDI-DI
ANIOS RL	ANIOS	Rinsing agent invasive	04 1x1000L	359761LA01501ILIMA
ANIOS RL	ANIOS	Rinsing agent invasive	15C 2x5L	
ANIOS RL	ANIOS	Rinsing agent invasive	18 1x25L	
ANIOS RL	ANIOS	Rinsing agent invasive	24 1x10L	
ANIOS RL	ANIOS	Rinsing agent invasive	38 2x5L	
ANIOS RL	ANIOS	Rinsing agent invasive	271 1x25L	
ANIOS RL	ANIOS	Rinsing agent invasive	331 1x220L	