

TECHNICAL FILE - EU DECLARATION OF CONFORMITY (\mbox{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 RHW
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 14/12/2022		Sainghin 14/12/2022	
	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



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Medical Device	Brand	Device Subcategory	Packaging variant	Basic UDI-DI
ANIOS RHW	ANIOS	Rinsing agent invasive	09 1x60L	359761LA01501ILIMA
ANIOS RHW	ANIOS	Rinsing agent invasive	15 2x5L	
ANIOS RHW	ANIOS	Rinsing agent invasive	18 1x25L	
ANIOS RHW	ANIOS	Rinsing agent invasive	24 1x10L	
ANIOS RHW	ANIOS	Rinsing agent invasive	38 2x5L	
ANIOS RHW	ANIOS	Rinsing agent invasive	271 1x25L	
ANIOS RHW	ANIOS	Rinsing agent invasive	331 1x220L	