

	<b>Technical File - EU Declaration of Conformity</b>	D05208	
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We

Name + address + Single Registration Number of manufacturer:	<b>Soluscope SAS</b> <b>100 rue du Fauge ZI Les Paluds</b> <b>13400 Aubagne</b> <b>France</b>  <b>SRN not applicable yet</b>
Name + address + Single Registration Number of authorized representative:	Not Applicable



declare on our sole responsibility that

the medical device	SOLUSCOPE EZ
Type / Intended Use	Concentrated Cleaner, to be used exclusively in endoscope washer-disinfectors SOLUSCOPE SERIE 1, according to the user manual
Class Rule according to MDR Annex VIII	I 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

Aubagne, 03/09/2021	 Christian Jost, PRRC Christian Affre, C.E.O
Place, date	Name and function (Person Responsible for Regulatory Compliance)  Name and function (Legal Representative) 

Signed on behalf of: **Soluscope SAS**



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Medical Device	Brand	Device Subcategory	Part Number / SKU	Basic UDI-DI
SOLUSCOPE EZ	SOLUSCOPE	Detergent	248344444	359761SS01C150EXBP
SOLUSCOPE EZ	SOLUSCOPE	Detergent	24834447Q	359761SS01C150EXBP
SOLUSCOPE EZ	SOLUSCOPE	Detergent	2483444BR	359761SS01C150EXBP
SOLUSCOPE EZ	SOLUSCOPE	Detergent	2483444FG	359761SS01C150EXBP
SOLUSCOPE EZ	SOLUSCOPE	Detergent	2483444GZ	359761SS01C150EXBP
SOLUSCOPE EZ	SOLUSCOPE	Detergent	2483444UP	359761SS01C150EXBP
SOLUSCOPE EZ	SOLUSCOPE	Detergent	2483444ZH	359761SS01C150EXBP

