



**DECLARATION DE CONFORMITE UE SELON LA DIRECTIVE 93/42/CEE**  
**EU DECLARATION OF CONFORMITY ACCORDING TO DIRECTIVE 93/42/CEE**

Document code	VERSION	DATE D'APPLICATION	DATE DE RÉVISION	PAGES
F-MET114-A	01	26 May 2023	25 May 2025	1/3

<b>Nom du fabricant</b> <i>Manufacturer's name</i>	<b>ITENA CLINICAL</b>
<b>Adresse du fabricant</b> <i>Manufacturer's address</i>	Central Parc- Bâtiment B – 97 Allée de la Louve – 93420 Villepinte – France
<b>Domaine d'application</b> <i>Scope of application</i>	<b>Dossier Technique EF-38 REFLECTYS FLOW</b> Se référer à la liste des produits associés en annexe.  <i>Technical File EF-38 REFLECTYS FLOW</i> Refer to the associated list of products in the appendix.
<b>Organisme Notifié</b> <i>Notified Body</i>	Nom / Name: ICIM S.P.A Numéro d'identification / Identification number : <b>0425</b>
<b>Numéro de Certificat</b> <i>Certificate No.</i>	0425-MED-004026-00

ITENA CLINICAL déclare et atteste sous sa seule responsabilité que les **dispositifs médicaux REFLECTYS FLOW**, listés ci-après, satisfont aux dispositions applicables et aux exigences de la Directive 93/42/CEE.

**CONFORMEMENT A L'ARTICLE R.5211-65 et R.5211-70 DU LIVRE II CINQUIEME PARTIE DU CODE DE LA SANTE PUBLIQUE ANNEXE II (SECTION 4 EXCLUE) DE LA DIR 93/42/EEC incluant la Directive 2007/47CE)**

De ce fait, nous estimons remplir les obligations des exigences essentielles selon l'annexe I de la Directive 93/42/EEC et que les dispositifs compris dans ce document remplissent les exigences de la directive.

*ITENA CLINICAL declares and certifies under its sole responsibility that the **medical devices REFLECTYS FLOW**, listed below, comply with the applicable provisions and requirements of Directive 93/42/CEE.*

**ACCORDING TO ANNEX II (EXCLUDING SECTION 4) OF THE COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES INCLUDING 2007/47/EC**

*Therefore, we estimate to fill the obligations of the essential requirements according to the appendix I with the DIR 93 / 42 / EEC and that the devices covered under this document meet the applicable provisions of the directive.*

Villepinte,  
01/06/2023  
Alexandre MULHAUSER  
CEO

**ITENA CLINICAL**  
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93420 VILLEPINTE - FRANCE  
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NOM DU PRODUIT NAME OF THE PRODUCT	REF	DESIGNATION DESIGNATION	CLASSE & REGLE DE CLASSIFICATION CLASS & CLASSIFICATION RULE	CODE GMDN
REFLECTYS FLOW	Voir ci-joint See attachment – liste references Reflectys	Matériaux d'obturation. Filling material.	Classe <b>IIA</b> selon la règle <b>8</b> de l'Annexe IX de la Directive 93/42/CEE  Class <b>IIA</b> according to rule <b>8</b> of Annex IX of Directive 93/42/CEE	35870



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Liste des références Reflectys Flow  
Reflectys Flow reference list

<b>REFLECTYS FLOW</b>	
<b>FWTYS-A1</b>	1 syringe (2g) Reflectys Flow A1+ 10 tips (2) 0.9 mm
<b>FWTYS-A2</b>	1 syringe (2g) Reflectys Flow A2 + 10 tips (2) 0.9 mm
<b>FWTYS-A3</b>	1 syringe (2g) Reflectys Flow A3 + 10 tips (2) 0.9 mm
<b>FWTYS-A3.5</b>	1 syringe (2g) Reflectys Flow A3,5 + 10 tips (2) 0.9 mm
<b>FWTYS-B2</b>	1 syringe (2g) Reflectys Flow B2 + 10 tips (2) 0.9 mm
<b>FWTYS-B3</b>	1 syringe (2g) Reflectys Flow B2 + 10 tips (2) 0.9 mm