



# 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	1/4

<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>	Dossier Technique <b>EF-37 REFLECTYS</b> Se référer à la liste des produits associés en annexe.  <i>Technical File <b>EF-37 REFLECTYS</b></i> <i>Refer to the associated list of products in the appendix.</i>
<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**, 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.

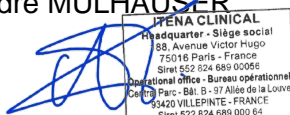
*ITENA CLINICAL declares and certifies under its sole responsibility that the **medical devices REFLECTYS**, listed below, comply with the applicable provisions and requirements of Directive 93/42/CEE.*

## 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,  
21/12/2023

Alexandre MULHAUSER  
CEO





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

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NOM DU PRODUIT NAME OF THE PRODUCT	REF	DESIGNATION DESIGNATION	CLASSE & REGLE DE CLASSIFICATION CLASS & CLASSIFICATION RULE	CODE GMDN
REFLECTYS	Voir ci-joint See attachment – liste references Reflectys	Composite universel pour les restaurations antéro-postérieures. <i>Universal composite for anteroposterior restorations</i>	Classe <b>IIA</b> selon la règle <b>8</b> de l'Annexe IX de la Directive 93/42/CEE  <i>Class <b>IIA</b> according to rule <b>8</b> of Annex IX of Directive 93/42/CEE</i>	35870



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### Liste des références Reflectys

#### Reflectys reference list

<b>REFLECTYS</b>	
<b>SRTYS-A1</b>	1 syringe (4g) Reflectys A1 + 1 spatula
<b>SRTYS-A2</b>	1 syringe (4g) Reflectys A2 + 1 spatula
<b>SRTYS-A3</b>	1 syringe (4g) Reflectys A3 + 1 spatula
<b>SRTYS-A3.5</b>	1 syringe (4g) Reflectys A3.5 + 1 spatula
<b>SRTYS-A4</b>	1 syringe (4g) Reflectys A4 + 1 spatula
<b>SRTYS-B1</b>	1 syringe (4g) Reflectys B1 + 1 spatula
<b>SRTYS-B2</b>	1 syringe (4g) Reflectys B2 + 1 spatula
<b>SRTYS-B3</b>	1 syringe (4g) Reflectys B3 + 1 spatula
<b>SRTYS-C2</b>	1 syringe (4g) Reflectys C2 + 1 spatula
<b>SRTYS-C3</b>	1 syringe (4g) Reflectys C3 + 1 spatula
<b>SRTYS-D3</b>	1 syringe (4g) Reflectys D3 + 1 spatula
<b>SRTYS-BLC</b>	1 syringe (4g) Reflectys Bleach + 1 spatula
<b>SRTYS-E</b>	Shade for stratification Enamel_1 syringe (4g) + 1 spatula
<b>SRTYS-I</b>	Shade for stratification Incisal_1 syringe (4g) + 1 spatula
<b>SRTYS-P</b>	Shade for stratification Pedo_1 syringe (4g) + 1 spatula
<b>SRTYS-A20</b>	Shade for stratification Opaque A2_1 syringe (4g) + 1 spatula
<b>SRTYS-A30</b>	Shade for stratification Opaque A3_1 syringe (4g) + 1 spatula
<b>CPTYA-A1</b>	20 capsules (0,25g) Reflectys A1
<b>CPTYA-A2</b>	20 capsules (0,25g) Reflectys A2
<b>CPTYA-A3</b>	20 capsules (0,25g) Reflectys A3
<b>CPTYA-A3.5</b>	20 capsules (0,25g) Reflectys A3.5
<b>CPTYA-A4</b>	20 capsules (0,25g) Reflectys A4
<b>CPTYA-B1</b>	20 capsules (0,25g) Reflectys B1
<b>CPTYA-B2</b>	20 capsules (0,25g) Reflectys B2
<b>CPTYA-B3</b>	20 capsules (0,25g) Reflectys B3
<b>CPTYA-C2</b>	20 capsules (0,25g) Reflectys C2



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<b>CPTYS-C3</b>	20 capsules (0,25g) Reflectys C3
<b>CPTYS-D3</b>	20 capsules (0,25g) Reflectys D3
<b>CPTYS-BLC</b>	20 capsules (0,25g) Reflectys Bleach
<b>CPTYS-E</b>	Shade for stratification Enamel_20 capsules (0,25g)
<b>CPTYS-I</b>	Shade for stratification Incisal_20 capsules (0,25g)
<b>CPTYS-P</b>	Shade for stratification Pedo_20 capsules (0,25g)
<b>CPTYS-A2O</b>	Shade for stratification Opaque A2_20 capsules (0,25g)
<b>CPTYS-A3O</b>	Shade for stratification Opaque A3_20 capsules (0,25g)
<b>KTYS-4.1B</b>	Restoration Kit 4 Reflectys syringes (A2, A3, A3.5, B2) + 1 bonding Iperbond Ultra
<b>KTYS-7.2BE</b>	Stratification Kit 7 Reflectys syringes (A1, A2, A3, Opaque A2, Opaque A3, Enamel, Incisal) + 1 bonding Iperbond Ultra + 3 etching gel Dentoetch
<b>ECHRFLTYS</b>	Sample of the syringe Reflectys A3
<b>ECHCPTYS</b>	Sample of the capsules Reflectys A3
<b>ECHSRTYSA2</b>	Sample of the syringe Reflectys A2