



## DECLARATION CE DE CONFORMITE EC DECLARATION OF CONFORMITY

Nous, Société ITENA CLINICAL située au 188 Avenue Victor Hugo – 75016 Paris - France. Assurons et déclarons sous notre responsabilité que les dispositifs médicaux suivant appartiennent à la classe IIA et sont conformes aux exigences :

We, company ITENA CLINICAL, placed, 188 Avenue Victor Hugo – 75016 Paris - France, declare under our sole responsibility that the following medical devices are of class IIA and are in accordance with the requirements:

**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)**

**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**

| Nom/Name  | Designation                                  | Références/References                                            | Classe / Class<br>according to annex IX<br>of DIR 93/42/EEC<br>including 2007/47/CE) |
|-----------|----------------------------------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| REFLECTYS | Matériaux d'obturation / Filling<br>material | Voir ci-joint / see<br>attachment -Liste<br>références Reflectys | Classe IIa , règle 8<br>Class IIa, rule 8                                            |

De ce fait, nous estimons remplir les obligations des exigences essentielles selon l'annexe I de  
La DIR 93/42/EEC et que les dispositifs compris dans ce document remplissent les exigences de la directive.  
Cette déclaration est faite sous le **certificat N° 0425-MED-004026-00** délivré par notre Organisme Notifié :  
ICIM S.p.A., Piazza Don Enrico Mapelli, 75. 20099 SESTO SAN GIOVANNI (MI) sous le numéro CE 0425.

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.

This declaration is done under **certificate N° 0425-MED-004026-00** supported by Notified: ICIM S.p.A.,  
Piazza Don Enrico Mapelli, 75. 20099 SESTO SAN GIOVANNI (MI), under Number CE 0425

Fait à Paris, le 29/07/2020  
Done in Paris on 29/07/2020

Megan MARCELLIN  
Regulatory Affairs Officer

Declaration\_of\_conformity\_REFLECTYS \_July 2020

| <b>REFLECTYS</b>  |                                                                 |
|-------------------|-----------------------------------------------------------------|
| <b>SRTYS-A1</b>   | 1 syringue (4mg) Reflectys A1 + 1 spatula                       |
| <b>SRTYS-A2</b>   | 1 syringue (4mg) Reflectys A2 + 1 spatula                       |
| <b>SRTYS-A3</b>   | 1 syringue (4mg) Reflectys A3 + 1 spatula                       |
| <b>SRTYS-A3.5</b> | 1 syringue (4mg) Reflectys A3.5 + 1 spatula                     |
| <b>SRTYS-A4</b>   | 1 syringue (4mg) Reflectys A4 + 1 spatula                       |
| <b>SRTYS-B1</b>   | 1 syringue (4mg) Reflectys B1 + 1 spatula                       |
| <b>SRTYS-B2</b>   | 1 syringue (4mg) Reflectys B2 + 1 spatula                       |
| <b>SRTYS-B3</b>   | 1 syringue (4mg) Reflectys B3 + 1 spatula                       |
| <b>SRTYS-C2</b>   | 1 syringue (4mg) Reflectys C2 + 1 spatula                       |
| <b>SRTYS-C3</b>   | 1 syringue (4mg) Reflectys C3 + 1 spatula                       |
| <b>SRTYS-D3</b>   | 1 syringue (4mg) Reflectys D3 + 1 spatula                       |
| <b>CPTYS-A1</b>   | 20 capsules (0,25g) Reflectys A1                                |
| <b>CPTYS-A2</b>   | 20 capsules (0,25g) Reflectys A2                                |
| <b>CPTYS-A3</b>   | 20 capsules (0,25g) Reflectys A3                                |
| <b>CPTYS-A3.5</b> | 20 capsules (0,25g) Reflectys A3.5                              |
| <b>CPTYS-A4</b>   | 20 capsules (0,25g) Reflectys A4                                |
| <b>CPTYS-B1</b>   | 20 capsules (0,25g) Reflectys B1                                |
| <b>CPTYS-B2</b>   | 20 capsules (0,25g) Reflectys B2                                |
| <b>CPTYS-B3</b>   | 20 capsules (0,25g) Reflectys B3                                |
| <b>CPTYS-C2</b>   | 20 capsules (0,25g) Reflectys C2                                |
| <b>CPTYS-C3</b>   | 20 capsules (0,25g) Reflectys C3                                |
| <b>CPTYS-D3</b>   | 20 capsules (0,25g) Reflectys D3                                |
| <b>SRTYS-E</b>    | Shade for stratification Enamel_1 syringue (4mg) + 1 spatula -  |
| <b>SRTYS-I</b>    | Shade for stratification Incisal_1 syringue (4mg) + 1 spatula   |
| <b>SRTYS-P</b>    | Shade for stratification Pado_1 syringue (4mg) + 1 spatula      |
| <b>SRTYS-A20</b>  | Shade for stratification Opaque A2_1 syringue (4mg) + 1 spatula |
| <b>SRTYS-A30</b>  | Shade for stratification Opaque A3_1 syringue (4mg) + 1 spatula |
| <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 Pado_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<br>4 Reflectys syringes (A2, A3, A3.5, B2) + 1 bonding Iperbond Ultra                                                                     |
| <b>KTYS-7.2BE</b> | Stratification Kit<br>7 Reflectys syringes (A1, A2, A3, Opaque A2, Opaque A3, Enamel, Incisal)<br>+ 1 bonding Iperbond Ultra<br>+ 1 etching gel Dentoetch |
| <b>ECHRFLTYS</b>  | Sample of the syringue Reflectys A3                                                                                                                       |
| <b>EHCPTYS</b>    | Sample of the capsules Reflectys A3                                                                                                                       |
| <b>ECHSRTYSA2</b> | Sample of the syringue Reflectys A2                                                                                                                       |

*Reflectys consist in 37 references*

Megan MARCELLIN  
Regulatory Affairs Officer  
03/11/2020

