

**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 according to annex IX of DIR 93/42/EEC including 2007/47/CE)
REFLECTYS	Matériaux d'obturation / Filling material	Voir ci-joint / see attachment -Liste références Reflectys	Classe IIa , règle 8 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

REFLECTYS	
SRTYS-A1	1 syringue (4mg) Reflectys A1 + 1 spatula
SRTYS-A2	1 syringue (4mg) Reflectys A2 + 1 spatula
SRTYS-A3	1 syringue (4mg) Reflectys A3 + 1 spatula
SRTYS-A3.5	1 syringue (4mg) Reflectys A3.5 + 1 spatula
SRTYS-A4	1 syringue (4mg) Reflectys A4 + 1 spatula
SRTYS-B1	1 syringue (4mg) Reflectys B1 + 1 spatula
SRTYS-B2	1 syringue (4mg) Reflectys B2 + 1 spatula
SRTYS-B3	1 syringue (4mg) Reflectys B3 + 1 spatula
SRTYS-C2	1 syringue (4mg) Reflectys C2 + 1 spatula
SRTYS-C3	1 syringue (4mg) Reflectys C3 + 1 spatula
SRTYS-D3	1 syringue (4mg) Reflectys D3 + 1 spatula
CPTYS-A1	20 capsules (0,25g) Reflectys A1
CPTYS-A2	20 capsules (0,25g) Reflectys A2
CPTYS-A3	20 capsules (0,25g) Reflectys A3
CPTYS-A3.5	20 capsules (0,25g) Reflectys A3.5
CPTYS-A4	20 capsules (0,25g) Reflectys A4
CPTYS-B1	20 capsules (0,25g) Reflectys B1
CPTYS-B2	20 capsules (0,25g) Reflectys B2
CPTYS-B3	20 capsules (0,25g) Reflectys B3
CPTYS-C2	20 capsules (0,25g) Reflectys C2
CPTYS-C3	20 capsules (0,25g) Reflectys C3
CPTYS-D3	20 capsules (0,25g) Reflectys D3
SRTYS-E	Shade for stratification Enamel_1 syringue (4mg) + 1 spatula -
SRTYS-I	Shade for stratification Incisal_1 syringue (4mg) + 1 spatula
SRTYS-P	Shade for stratification Pedo_1 syringue (4mg) + 1 spatula
SRTYS-A20	Shade for stratification Opaque A2_1 syringue (4mg) + 1 spatula
SRTYS-A30	Shade for stratification Opaque A3_1 syringue (4mg) + 1 spatula
CPTYS-E	Shade for stratification Enamel_20 capsules (0,25g)
CPTYS-I	Shade for stratification Incisal_20 capsules (0,25g)
CPTYS-P	Shade for stratification Pedo_20 capsules (0,25g)

CPTYS-A2O	Shade for stratification Opaque A2_20 capsules (0,25g)
CPTYS-A3O	Shade for stratification Opaque A3_20 capsules (0,25g)
KTYS-4.1B	Restoration Kit 4 Reflectys syringes (A2, A3, A3.5, B2) + 1 bonding Iperbond Ultra
KTYS-7.2BE	Stratification Kit 7 Reflectys syringes (A1, A2, A3, Opaque A2, Opaque A3, Enamel, Incisal) + 1 bonding Iperbond Ultra + 1 etching gel Dentoetch
ECHRFLTYS	Sample of the syringue Reflectys A3
EHCPTYS	Sample of the capsules Reflectys A3
ECHSRTYSA2	Sample of the syringue Reflectys A2

Reflectys consist in 37 references

Megan MARCELLIN
Regulatory Affairs Officer
03/11/2020

