

**DECLARATION OF CONFORMITY FOR THE FAMILY OF MEDICAL DEVICES
"FIXATION DEVICES"**

whose trade names are specified in the annex, to the General Safety and Performance Requirements referred to in Annex I of Regulation (EU) 2017/745 on medical devices and subsequent amendments and corrections.

The undersigned PLASTOD S.p.A., with registered office in Via Masetti, 7 - 40012 Lippo di Calderara di Reno (BO) - Italy, manufacturer of the devices called "FIXATION DEVICES" whose trade names are shown in the annex,

declares under its own responsibility that the devices referred to in the object meet all the General Safety and Performance Requirements required by Annex I of Regulation (EU) 2017/745 and subsequent amendments and corrections.

For this purpose, it guarantees and declares under its own responsibility the following:

1. That the devices in question meet the applicable provisions of Regulation (EU) 2017/745 and subsequent amendments and corrections, as required by the procedure of Article 52 "Conformity assessment procedures", point 7 of the aforementioned Regulation.
2. That the devices in question are to be considered as belonging to Class I according to Rule 1 of Annex VIII of Regulation (EU) 2017/745.
3. That the devices in question are put on the market in NON-STERILE packaging.
4. That the devices are produced in various versions and the list of corresponding commercial names is attached.
5. That the design and manufacturing process is conducted in compliance with the requirements of the company's Quality Management System, in accordance with the requirements of Annex IX of Regulation (EU) 2017/745.
6. That PLASTOD S.p.A. undertakes to preserve and keep available to the Competent Authority the product Technical Documentation, specified in Annexes II and III of Regulation (EU) 2017/745, for a period of 10 years from the last date of placing on the market of the last batch of the product.
7. That the devices comply with the state of the art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.
8. That the company's Quality Management System complies with the UNI EN ISO 9001: 2015 standards (ref. Certificate n. 19344-A, current issue of 30/07/2021) and UNI CEI EN ISO 13485: 2016 (ref. Certificate n. 19344-M, current issue of 30/07/2021).
9. That PLASTOD S.p.A. has already notified the Italian Competent Authority of the placing on the market of the aforementioned devices. It also declares to have established and to maintain an appropriate procedure to ensure the post-marketing surveillance required by Regulation (EU) 2017/745 on medical devices.

Plastod S.p.A.

Via Walter Masetti, 7
40012 - Lippo di Calderara di Reno
Bologna - ITALY

Capitale Sociale € 3.857.144,00 I.V.



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SDI: 7HE8RN5
R.E.A. Bologna 92164

N. Mecc. 80017328
Aut. Ministeriale 3554/P

The content of this declaration of conformity, issued under the sole responsibility of the manufacturer PLASTOD S.p.A., is confirmed at each code release and at each batch release of the indicated devices, produced starting from 30/07/2021.

This declaration is valid for a maximum of five years from the date of issue.

Attachments:

- List of trade names referred to in this Declaration.

In witness whereof

PLASTOD S.p.A.

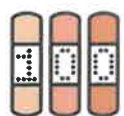
On behalf of the Legal Representative

A handwritten signature in blue ink, appearing to read "U. Dotta", written over a horizontal line.

Umberto Dotta (BoD Vice-President)

Place, date of issue and Ed / Rev. of the declaration:

Lippo di Calderara di Reno, 30/07/2021 - Ed./Rev. 01/1



100 anni di Plastod
100 years of Plastod
1915 - 2015

Plastod S.p.A.
Soggetta a direzione e coordinamento della Finanziaria Plastod - società di partecipazioni industriali S.r.l.

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SISTEMI DI GESTIONE
QUALITA' CERTIFICATI
UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016

	Tipo di documento: LISTA PRODOTTI/ PRODUCTS LIST	Data prima edizione: 03/05/21
		Numero: Annex I TD 01-2
		Ed / Rev: 01/1 del 30/07/21
Prodotto: Dispositivi di fissaggio (TD 01-2) – Fixation devices		
Famiglia prodotti: Dispositivi medici - medicazioni		

Fabbricante: PLASTOD S.p.A., Via W. Masetti, 7 - 40012 Lippo di Calderara di Reno (BO) – Italia
 Manufacturer

Distributore: PLASTOD S.p.A., Via W. Masetti, 7 - 40012 Lippo di Calderara di Reno (BO) – Italia
 Distributor

Codice Plastod Plastod code	REF	Marchio Brand	Descrizione Description	Dimensione Size	Scheda tecnica TDS	Confezione (pz/ast) Box (pcs/box)	BASIC UDI-DI
Z0525HP-2	00331	Hyporplast	Rolls in tnt estensibile bianco	mt 5x2,5 cm	19-012	1	8015143M04010201H4
Z0505THP-2	00333	Hyporplast	Rolls in tnt estensibile bianco	mt 5x5 cm	19-012	1	8015143M04010201H4
Z1005THP-2	00330	Hyporplast	Rolls in tnt estensibile bianco	mt 10x5 cm	19-012	1	8015143M04010201H4
Z1010THP-2	00332	Hyporplast	Rolls in tnt estensibile bianco	mt 10x10 cm	19-012	1	8015143M04010201H4
Z1015THP-2	00334	Hyporplast	Rolls in tnt estensibile bianco	mt 10x15 cm	19-012	1	8015143M04010201H4
Z1020THP-2	00336	Hyporplast	Rolls in tnt estensibile bianco	mt 10x20 cm	19-012	1	8015143M04010201H4
RTR05FHP-2	00110	Hypor Textile Pink	Cerotti su tubetto in tela rosa adesivo bianco	mt 5x1,25 cm	06-015-6	18	8015143M05010100HE
RTR06FHP-2	00112	Hypor Textile Pink	Cerotti su tubetto in tela rosa adesivo bianco	mt 5x2,5 cm	06-015-6	12	8015143M05010100HE
RTR07FHP-2	00114	Hypor Textile Pink	Cerotti su tubetto in tela rosa adesivo bianco	mt 5x5 cm	06-015-6	6	8015143M05010100HE
RNB05FHP-2	00130	Hypor Por	Cerotti su tubetto in Tnt sottile bianco	mt 5x1,25 cm	12-005-6	18	8015143M05010100HE
RNB06FHP-2	00132	Hypor Por	Cerotti su tubetto in Tnt sottile bianco	mt 5x2,5 cm	12-005-6	12	8015143M05010100HE
RNB07FHP-2	00134	Hypor Por	Cerotti su tubetto in Tnt sottile bianco	mt 5x5 cm	12-005-6	6	8015143M05010100HE
RSB05FHP-2	00140	Hypor Silk	Cerotti su tubetto in seta artificiale adesivo trasp.	mt 5x1,25 cm	07-005-6	18	8015143M05010100HE
RSB06FHP-2	00142	Hypor Silk	Cerotti su tubetto in seta artificiale adesivo trasp.	mt 5x2,5 cm	07-005-6	12	8015143M05010100HE
RSB07FHP-2	00144	Hypor Silk	Cerotti su tubetto in seta artificiale adesivo trasp.	mt 5x5 cm	07-005-6	6	8015143M05010100HE
RPT05FHP-2	00152	Hypor Clear	Cerotti su tubetto in PE trasparente microperforato	mt 5x1,25 cm	42-343-6	18	8015143M05010100HE
RPT06FHP-2	00154	Hypor Clear	Cerotti su tubetto in PE trasparente microperforato	mt 5x2,5 cm	42-343-6	12	8015143M05010100HE
RPT07FHP-2	00156	Hypor Clear	Cerotti su tubetto in PE trasparente microperforato	mt 5x5 cm	42-343-6	6	8015143M05010100HE

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RTB05OHP-2	00161	Hypor Textile White	Cerotti su tubetto in tela bianco	mt 5x1,25 cm	06-005-6	24	8015143M05010100HE
RTB06OHP-2	00163	Hypor Textile White	Cerotti su tubetto in tela bianco	mt 5x2,5 cm	06-005-6	12	8015143M05010100HE
RTB07OHP-2	00165	Hypor Textile White	Cerotti su tubetto in tela bianco	mt 5x5 cm	06-005-6	6	8015143M05010100HE
RNB05FHP-2	00180	Hypor Por	Cerotti su tubetto in Tnt sottile bianco	mt 9,14x1,25 cm	12-005-6	24	8015143M05010100HE
RNB06FHP-2	00181	Hypor Por	Cerotti su tubetto in Tnt sottile bianco	mt 9,14x2,5 cm	12-005-6	12	8015143M05010100HE
RNB07FHP-2	00183	Hypor Por	Cerotti su tubetto in Tnt sottile bianco	mt 9,14x5 cm	12-005-6	6	8015143M05010100HE
RSB10OHP-2	00190	Hypor Silk	Cerotti su tubetto in seta artificiale adesivo trasparente	mt 9,14x1,25 cm	07-005-6	24	8015143M05010100HE
RSB11OHP-2	00191	Hypor Silk	Cerotti su tubetto in seta artificiale adesivo trasparente	mt 9,14x2,5 cm	07-005-6	12	8015143M05010100HE
RSB12OHP-2	00193	Hypor Silk	Cerotti su tubetto in seta artificiale adesivo trasparente	mt 9,14x5 cm	07-005-6	6	8015143M05010100HE
RPT10OHP-2	00200	Hypor Clear	Cerotti su tubetto in PE trasparente microperforato	mt 9,14x1,25 cm	42-343-6	24	8015143M05010100HE
RPT11OHP-2	00201	Hypor Clear	Cerotti su tubetto in PE trasparente microperforato	mt 9,14x2,5 cm	42-343-6	12	8015143M05010100HE
RPT12OHP-2	00203	Hypor Clear	Cerotti su tubetto in PE trasparente microperforato	mt 9,14x5 cm	42-343-6	6	8015143M05010100HE
ZTB1425HP-2	00690	Hypor Sport	Nastro per applicazioni sportive	mt 14 x 2,5 cm	06-005-5	48	8015143M05010100HE
ZTB1438HP-2	00692	Hypor Sport	Nastro per applicazioni sportive	mt 14 x 3,8 cm	06-005-5	30	8015143M05010100HE
ZTB1450HP-2	00694	Hypor Sport	Nastro per applicazioni sportive	mt 14 x 5 cm	06-005-5	24	8015143M05010100HE