

**DECLARATION OF CONFORMITY FOR THE FAMILY OF MEDICAL DEVICES
"ORTHOPTIC EYE PATCHES"**

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 "ORTHOPTIC EYE PATCHES" 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.

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.

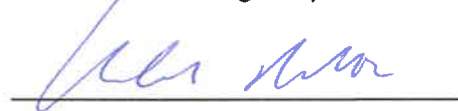
Attachments:

- List of trade names referred to in this Declaration.

In witness whereof

PLASTOD S.p.A.

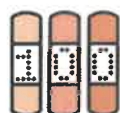
On behalf of the Legal Representative



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.

Contacts
web site: www.plastod.com / e-mail: info@plastod.com
pec: amministrazione.plastod@pec.it
Tel. 051.64.65.811 / Fax 051.64.66.401

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: 25/05/21
		Numero: Annex I TD 01-3
		Ed / Rev: 01/1 del 30/07/21
Prodotto: Cerotti oculari ortottici (TD 01-3) – Orthophtic eye patches		
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	Dimension e Size	Scheda tecnica TDS	Confezione (pz/ast) Box (pcs/box)	BASIC UDI-DI
COMORTJHP-2	00252	Hypordress Eye Therapy	Compresse ortottiche junior	48x60 mm	82-255	21	8015143M04030300HV
COMORTRHP-2	00254	Hypordress Eye Therapy	Compresse ortottiche regular	57x72 mm	82-255	21	8015143M04030300HV
COMORTLHP-2	00255	Hypordress Eye Therapy	Compresse ortottiche large	57x80 mm	82-255	21	8015143M04030300HV
COMORTSRHP-2	00256	Hypordress Eye Therapy	Compresse ortottiche regular kids	57x72 mm	82-655	21	8015143M04030300HV