

Declaration of Conformity

HEPARINE 500 U.I.



BASIC UDI DI: **0761209800HPR1VV**

Single Registration Number (SRN) Manufacturer: **CH-MF-000007729**

Single Registration Number (SRN) EU-Authorised Representative: **DE-AR-000007649**

EU-Authorised Representative:
Name: Sintetica GmbH
State: Germany (EU)
City: Munster
Federal State: Nordrhein-Westfalen
Postal code: 48155
Street, house no: Albersloher Weg 11

Batch n°: 21204 **Expiry date: 06/2026**

Mendrisio (CH), date: 20/07/2021

The undersigned SINTETICA SA, based in Mendrisio (CH), manufacturer of the medical device HEPARINE 500 U.I., declares under its own responsibility that the device at hand is comply with all requirements as per Directive 93/42/EEC and subsequent amendments and additions, transposed in Italy with the Italian Legislative Decree n. 46 of 24 February 1997 and its subsequent amendments and additions.

For this purpose, SINTETICA SA declares under its own responsibility that the medical device HEPARINE 500 U.I.:

- Belongs to the class III;
- It is marketed in ampoules containing the product as sterilized;
- Is collected in a non-sterile packaging;
- It is not a measuring instrument;
- It is not intended for clinical investigations;
- It is intended for single use.

Furthermore:

- SINTETICA SA established internal procedures aimed to guarantee, as per own know how on this field, specific verifications and proper controls before the markets release and after the market release;
- SINTETICA SA established to keep and make available to the competent authorities, the technical documentation of the product at hand, for a period of 10 years from the last placing of the product on the market.

For this reason, it is deemed that the Medical Device Heparine 500 U.I. is manufactured in compliance with the requirements as per Directive 93/42/EEC and subsequent amendments and additions, transposed in Italy with the Italian Legislative Decree n. 46 of 24 February 1997 and its subsequent amendments and additions; in addition, it is deemed that the medical device at hand will be released with the CE marking according to the regulation above mentioned.



Sintetica S.A.
Pharmaceuticals
CH-6850 Mendrisio

SINETICA SA
Qualified Person

P.O.

A handwritten signature in blue ink, which appears to read 'Sara Ficarelli', is written over the printed name 'P.O.'.