

UE Declaration of Conformity

Manufacturers Name:	Plastifil SA
Manufacturers Address:	Piazzale Roncàa, 2 CH-6850 Mendrisio
SRN (Single Registration Number):	NA
Authorized Representative Name and address (if applicable):	NA
Basic UDI-DI:	NA
Name of the Product/Device:	See attachment
Product code:	See attachment
Classification:	Class I
Notified Body name:	Without NB involvement
Notified Body Address:	Without NB involvement
Notified Body Identification number:	Without NB involvement
Conformity assessment route:	Plastifil SA does not mark their products according to the Regulation MDR 2017/745, because the products are: <u>Class I</u> : UE conformity declaration according to annex VIII + annex II

This declaration of conformity is issued under the sole responsibility of Plastifil SA. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (UE) MDR 2017/745 for medical devices and is also conform to Directive (CE) 1907/2006 (Reach) and Directive (UE) 2011/65 Rohs.

This declaration is supported by the Quality System approval to ISO 9001:15 issued by SQS Switzerland.

All supporting documentation is retained at the premises of the manufacturer.

Signature QA:

Place and date of issue:


Plastifil SA
6850 MENDRISIO

Mendrisio, 18.10.2023

Attachment to declaration of conformity

Reference number	Description
0200000259	Bettbogen
0200000453A-00	Instrumentenboy, verchromt, Tablar Melamin beschichtet, 420 x 620 x 800 mm
0200000443A-00	Instrumentenboy, verchromt, Tablar Melamin beschichtet, 520 x 520 x 800 mm
0200000454A-00	Instrumentenboy, verchromt, Tablar Melamin beschichtet, 520 x 770 x 800 mm
0200000456A-01	Instrumentenboy, Edelstahl, Tablar Edelstahl, 420 x 620 x 800 mm
0200000457A-01	Instrumentenboy, Edelstahl, Tablar Edelstahl, 520 x 520 x 800 mm
0200000458A-01	Instrumentenboy, Edelstahl, Tablar Edelstahl, 520 x 770 x 800 mm
0200000259	Bettbogen
0200000453A-00	Instrumentenboy, verchromt, Tablar Melamin beschichtet, 420 x 620 x 800 mm