



Megapharma Ospedaliera s.r.l.

capitale sociale € 50.000,00 · Reg. Imp. TV 25056 · R.E.A. 185002 · C.F. e Part. IVA 02032400265 · cod. fatturazione W7YVJK9
sede legale e magazzino: via Asolana, 26/b loc. Crespano · 31017 Pieve del Grappa (TV) · ID PEPPOL 0211:IT02032400265
uffici e recapito corrispondenza: via Molinetto, 28 loc. Crespano · 31017 Pieve del Grappa (TV) · Italia
tel. +39 0423 538746 · fax +39 0423 538748 · info@megapharma.it · megapharma@pcert.it · www.megapharma.it

EU DECLARATION OF CONFORMITY

This EU Declaration of Conformity is released under the Manufacturer responsibility only, the document is in conformity with what established in the enclosure IV of the EU Regulation 2017/745 about Medical Devices.

<i>Manufacturer</i>	Megapharma Ospedaliera s.r.l.
<i>Unique registration number</i>	IT-MF-000010739
<i>headquarters</i>	Via Asolana n. 26/b - loc. Crespano 31017 Pieve del Grappa (TV) - Italia
<i>Point of contact</i>	tel. +39 0423 538746 fax +39 0423 538748 e-mail info@megapharma.it e-mail PEC megapharma@pcert.it
<i>Device's name</i>	Plaster cast shoes
<i>Device's code</i>	04SG1034 04SG1035 04SG1036 04SG1037 04SG1038 04SG1039 04SG1040 04SG1041 04SG1042 04SG1043 04SG1044 04SG1045 04SG1046 04SG1047
<i>Destination of use</i>	Protection of the plaster cast and prevention of slipping on leaning
<i>Basic UDI-DI (GMN)</i>	80569779804SGHK
<i>Risk's class</i> I (no sterilized)	<i>Classification regulation (Enclosure VIII)</i> 1
<i>CS (Common Specifications) used</i>	-
<i>Armonized rules applied</i>	UNI CEI EN ISO 13485 - UNI CEI EN ISO 14971 - UNI CEI EN ISO 15223-1 - UNI EN 1041 - ISO 10993-1

The manufacturer Megapharma Ospedaliera claims, under its own responsibility, that the Medical Device in question, respects the EU Regulation 2017/745 about Medical Devices and that it satisfies the general safety and performance requirements of the enclosure I of the overmentioned Regulation.

The manufacturer claims too that its Quality Management System is certified in conformity with the Regulation UNI CEI EN ISO 13485.

Pieve del Grappa, 28th February 2025

The President
(Antonio Petranich)