S. Giuliano di Castelvetro (PC), 01 Agosto 2012

# DECLARATION OF CONFORMITY CE

**Biomatrix S.r.l.** registered office Corso Garibaldi, 14 – 26100 – Cremona – ITALY

**DECLARES**

under its proprietary liability, that the product called

**Operating room cabinet - art. Bio1012.A**

is accordant to the estimated requirements from the 93/42/CEE directive, for this reason is saleable with its CEE brand according to the art. 7 of the same directive. In particular:

- the medical product satisfy the essential requirements required from the attachment I of the 93/42/CEE directive
- the medical product has to be considered in all its applications belonging to the Class I according the applications rules of the IX attachment of the 93/42/CEE directive
- the medical product is provided in a not sterile packet
- the medical product is reusable
- the medical product does not have function of measure
- the medical product is not fated for clinical research
- the producer has regularly registered the medical product to the Italian Ministry of Health
- the producer has regularly worked the technical file of the construction according to the attachment VII of the 93/42/CEE directive
- the producer commits to make a disposition the technical file to the Competent Authority and Notified Organizations for a 5 years period from the date of the manufacture of the last batch of production

The Managing Director Biomatrix S.r.l.
(Mrs. Maria Grazia Mancini)

**Sede operativa**
Via Maffini, 23
29010 San Giuliano di Castelvetro (PC)
Tel. 0523.826619 Fax 0523.826728
E-mail info@biomatrix.it
Web www.biomatrix.it

BioMatrix

S. Giuliano di Castelvetro (PC),
2012 m. Rugpjūčio mėn. 1 d.

# CE ATITIKIMO DEKLARACIJA

**Biomatrix S.r.l.,** registruota adresu Corso Garibaldi, 14 – 26100 – Cremona – ITALY

**PATVIRTINA**

kad nurodytas produktas

**Operacinės spinta - modelis Bio1012.A**

atitinka pagrindinius 93/42/CEE direktyvos reikalavimus, taip pat šios direktyvos 7 straipsnio reikalavimus. Būtent:

- produktas atitinka pagrindiniams 93/42/CEE direktyvos I priedo reikalavimams
- medicininis produktas turi būti aprašytas pagal pagrindines 93/42/CEE direktyvos I Klasės produktų IX priedo taisykles
- medicininis produktas yra pristatomas nesterilioje pakuotėje
- medicininis produktas yra daugkartinio naudojimo
- medicininis produktas neatlieka matavimo funkcijos
- medicininis produktas n4ra skirtas klinikiniams tyrimams atlikti
- produktas yra reguliariai registruojamas Italijos Sveikatos Ministerijos medicininių produktų registre
- gamintojas nuolat atnaujina techninius failus pagal 93/42/CEE direktyvos VII priedo reikalavimus
- gamintojas įsipareigoja atnaujinti ir atiduoti techninius failus kas 5 metus Notifikacijos tarnyboms

The Managing Director Biomatrix S.r.l.
(Mrs. Maria Grazia Mancini)

/štampas; parašas/