CE DECLARATION OF CONFORMITY

Declaration of Conformity for the disposables named

“Pouches & Reels for Sterilization, Paper & Film, Non-woven Pouches”

manufactured by the company E-LINES.r.l., according to the European Directive 93/42/EECand integrations(ex. European Directive 2007/47/EC),concerning the medical devices of Class I non-sterile (Annex IX, Rule n. 1).

The undersigned company E-LINE S.r.l, situated in Via Soncino, 24050 Torre Pallavicina (BG), Italy, producer of medical disposables named “pouches and reels for the sterilization”, declares as its own responsibility, that the disposables as above satisfy all the applicable dispositions of the European Directive 93/42/EEC, integrations (ex. European Directive 2007/47/EC) and following modifications concerning medical devices.

To this purpose, E-LINE S.r.l. guarantees and declares that:

- The medical devices in hand satisfy the essential requirements referred to the attachment I of the above mentioned Directive
- The medical devices in hand have to be considered as belonging to Class I
- The medical devices in hand are not instruments for measuring
- The medical devices in hand have not to be used for hospital investigations
- The medical devices in hand conform to regulations UNI EN 868:5
- The medical devices in hand conform to regulations UNI EN ISO 11607: 1-2
- The medical devices in hand conform to regulations ISO 11140-1

It is finally declared, that the undersigned company will keep all documents referred to the attachment VII of the European Directive 93/42/EEC and integrations (European Directive 2007/47/EC) at disposal of competent Authorities for a periodof 5 years, beginning from the last date of production of medical devices.

Ref. Invoice .... of the .... .

E-LINE S.r.l.
Torre Pallavicina, Italy
15/10/2014

E-line S.r.l.
Via Soncino
24050 Torre Pallavicina (BG)
ITALY
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CERTIFICATO DEL SISTEMA DI GESTIONE PER LA QUALITÀ

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Si dichiara che il sistema di gestione per la Qualitá dell'Organizzazione:
We certify that the Quality Management System of the Organization:

Reg. No: 9886 – A

E.LINE S.r.l.

Indirizzo/*Address*:

Via Soncino S/N
24050 Torre Pallavicina BG Italia

È conforme alla norma/*Is in compliance with the standard:*

UNI EN ISO 9001:2008
ISO 9001:2008

Per i seguenti prodotti-servizi/*For the following products-services:*

Sviluppo e produzione di buste e rotoli per il confezionamento e sterilizzazione di dispositivi medici
Commercializzazione dispositivi medici monouso
Design and manufacturing of reels and pouches as packaging material for the sterile treatment of medical devices
Sales of disposable medical devices

EA: 07 , 29 a

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti essenziali CERMET.
Maintenance of the certification is subject to annual survey and dependent upon the observance of CERMET basic requirements.

La data di rilascio di questo certificato corrisponde alla data di primo rilascio da parte di altro Ente accreditato
The date of issuance of this certificate is the date of first issue by another accredited body

Rilascio certificato/*Certificate issuance:* **2009-08-07**
Ultima modifica/*Last modification:* **2012-08-06**
Prossimo rinnovo/*Following renewal:* **2015-08-05**

Direttore Commerciale e Operativo
Sales and Operations Manager
Giampiero Belcredi

Direttore Generale
General Manager
Rodolfo Trippodo

SGQ N° 007A FSM N° 004I
SGA N° 010D SSI N° 006G
PRD N° 069B

CERMET
Certification and research for quality

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