MEDICOR MEDITŰ KFT.

Declaration of Conformity

The undersigned declares that the goods described below are manufactured by our company (description of the goods, quantitiy, reference to the invoice.etc.): Surgical needle (Annex I.)

Placeof production: MEDICOR MEDITŰ Kft H-6900 Makó, Rákos út 6.

Short description of the manufacturing procedure:

In accordance with technology no. MU-7147:

The country of origin of the goods: HUNGARY

and the goods fully comply with the requirements of the non preferential rules of origin laid down in the articles 22-26 of the council regulation (CE)

No. 2913/92 (Community Customs Code) and/or Annex 10 or 11 to the council regulation (EC) No. 2454/93 (Implementing Provisions of the Community Customs Code).

Moreover, these products are manufactured by a company certified under

ISO9001:2008, which products are classified as Class I. invasive devices by

the EÜM Decree No. 4/2009 (III.17.) implemented under Directives (EEC)

No. 93/42. (Annex No.9.III/2.2.6/b, of the Decree EÜM No. 4/2009.III.17.)

The undersigned declares that the infromation given above is true and correct.

He undetakes to provide any further proof to this declaration if required by

the Chamber of Commerce and Industry.

MEDICOR MEDITÜ Sebészeti Varrótli Gyártó Kft. 6900 Makó, Rákosi út 6. Adószám: 10471773-2-06

Makó 2018.02.06.

MEDICOR MEDITÚ KŘ

6900 Makó, Rákosi út 6.

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managing director

H-6900 Makó, Rákosi út 6. Telefon /Fax: (62) 510-701 E-mail: meditu@invitel.hu Internet: www.meditu.hu.



Manufacturer's Declaration

The undersigned declares that the goods described below are manufactured by our company (description of the goods, quantity, reference to the invoice, etc.):

Surgical needle,

Place of production: MEDICOR MEDITU Kft. H-6900 Makó, Rákosi út 6.

Short description of the manufacturing procedure:

In accordance with technology no. MU-7147:

The country of origin of the goods: Hungary

and the goods fully comply with the requirements of the non preferential rules of origin laid down in the articles 22-26 of the council regulation (EC) No. 2913/92 (Community Customs Code) and/or Annex 10 or 11 to the council regulation (EC) No. 2454/93 (Implementing Provisions of the Community Customs Code). Moreover, these products are manufactured by a company certified under ISO 9001:2008, which products are classified as Class I. invasive devices by the EÜM Decree No. 4/2009. (III.17.) implemented under Directives (EEC) No. 93/42. (Annex No.9. III/2.2.6/b. of the Decree EÜM No. 4/2009. (III.17.).

The undersigned declares that the information given above is true and correct.

He undertakes to provide any further proof to this declaration if required by the Chamber of Commerce and Industry.

Makó, 2017.01.31. MEDICOR MEDITŰ Kft. 6900 Makó, Rákosi út 6.

Csongor György managing director

MEDICOR MEDITŰ Kft. 6900 Makó, Rákosi út S.

Place and date, company name and address

Name, position in company, signature