

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1824252**

Certificate Holder: **MEDITŰ Kft.**
Rákosi út 6.
H - 6900 MAKÓ
Hungary



Scope: production and distribution of surgical needles.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 08-01-2019 until 07-01-2022.

01-08-2019

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

MEDICOR MEDITŰ KFT.

Declaration of Conformity

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 (Annex I.)

Place of production: MEDICOR MEDITŰ 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 (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 EŰM Decree No. 4/2009 (III.17.) implemented under Directives (EEC) No. 93/42. (Annex No.9.III/2.2.6/b, of the Decree EŰM No. 4/2009.III.17.)

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

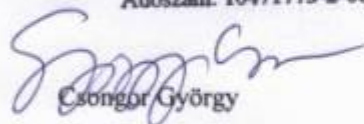
He undertakes to provide any further proof to this declaration if required by the Chamber of Commerce and Industry.

Makó 2018.02.06.

MEDICOR MEDITŰ Kft

6900 Makó, Rákosi út 6.

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


Csongor György

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

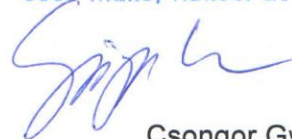
and the goods fully comply with the requirements of the non preferential rules of origin laid down in the articles 22-26 of the council regulation (EC) No. 2913/92 (Community Customs Code) and/or Annex 10 or 11 to the council regulation (EC) No. 2454/93 (Implementing Provisions of the Community Customs 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 MEDITÚ Kft.
6900 Makó, Rákosi út 6.

MEDICOR MEDITÚ Kft.
6900 Makó, Rákosi út 6.



Csongor György
managing director

Place and date, company name and address

Name, position in company, signature