144885-19-05-18

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Kft. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Denti System Kft.

Headquarters: **6600 Szentes, Bese László u. 8., Hungary**

Scope:

Dental implant systems

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Denti Needle Implant System (DN, DNB, DF)	One-stage implant system	implanted denture	According to detailed list	II.b
Denti Root Form Plus Implant System (DR+)	Two-stage implant system	implanted denture	According to detailed list	II.b
Denti Bone Level Implant System (DBL)	Two-stage implant system	implanted denture	According to detailed list	II.b
Denti Kone (DK), Denti Pro (DP), Callus Pro(CP) Implant System	Two-stage implant system	implanted denture	According to detailed list	II.b

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 51-CE-190208

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

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CE Certiso Ltd.
NB2409
Notified Body

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