



DECLARATION OF CONFORMITY

MANUFACTURER:

Goldent Hungary Kft.
H-2120 Dunakeszi, Alagi majori út 3.
Hungary

PRODUCT:

Goldent Classic, Goldent Premium, Goldent Exclusive

CLASSIFICATION:

Class IIa, Rule 5 according to Annex IX of the MDD

DECLARATION:

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC (Annex: V) for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

MSZ EN ISO 9001:2009 – Quality management system certificate
MSZ EN ISO 13485:2012 – Quality management system certificate
EN ISO 14971:2000 – Application of risk management to medical devices
EN 980:2003 – Graphical symbols for use in the labelling of medical devices

NOTIFIED BODY:

CE Certiso Ltd.
H-2040 Budaörs, Gyár u. 2. BITEP, Gábor Dénes krt. 101.
Identification number: 2409

EC CERTIFICATE(S):

EN ISO 9001: 2008
93/42/EEC Annex V, Article 5 Quality Assurance System

Dunakeszi, 18th of May, 2015

Dr. József Stranigg
director

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