



KOVAL d.o.o.

Loka 9
3223 Loka pri Žusmu

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EC Declaration of Conformity ES Izjava o skladnosti

Manufacturer:

Koval d.o.o.

**Loka 8, SI-3323 Loka pri Žusmu
Slovenia**

We declare that the following equipment:

Model numbers:

TOILET CHAIR - FIX, art. No. 11004010

TOILET CHAIR - EL, art. No. 11004020

Description:

TOILET CHAIR – KOVAL

Complies with:

93/42/EEC - Medical Device Directive (MDD)

and also complies with the following standards:

- SIST EN ISO 14971:2012
- SIST EN 60601-1:2007
- SIST EN 60601-1-6:2010
- SIST EN 60601-2-52:2010

Postopek ocenjevanja skladnosti je v skladu z direktivo 93/42/EGS – priloga VII.

Process of evaluation is in accordance with directive 93/42/EEC – annex VII.

Harmonized Standards applied in order to verify compliance with directives:

Medical Device Directive (MDD)

Classification of the device: Class I

Authorized Signatory

Manufacturer: Koval d.o.o.

Name: Zdravko Zidar

Position: Director

KOVAL d.o.o.
PROIZVODNJA IN TRGOVINA
LOKA PRI ŽUSMU 3223
SLOVENIJA 3

Date of issue:

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Place of issue:

Loka pri Žusmu