UROMED
PRODUKTE FÜR DIE UROLOGIE

UROMED Kurt Drews KG · Meessen 7/11 · 22113 Oststeinbek

14.12.2021

Ihr Zeichen | Unser Zeichen | Durchwahl 040 / 713 007- | Datum

Declaration on the implementation of the requirements of Regulation (EU) 2017/745

Dear Sir or Madam,

We hereby confirm that the products supplied by UROMED Kurt Drews KG comply with the regulatory requirements of Regulation (EU) 2017/745 resp. Directive 93/42/EEC.

For all UROMED medical devices (with the exception of risk class I) a valid certificate according to Directive 93/42/EEC Annex II, which is valid until 27.05.2024, is available. For the products of risk class I, the conformity according to Regulation (EU) 2017/745 was declared in due time by 26.05.2021.

In June 2021, UROMED successfully passed the first MDR audit. The certification according to Regulation (EU) 2017/745 is in process at our Notified Body, whereby the examination of the technical documentation by the Notified Body is an ongoing process. Only after successful completion of the audit and the issuance of the corresponding certificate by the Notified Body, a declaration of conformity according to Regulation (EU) 2017/745 can be issued by UROMED Kurt Drews KG.

The valid certificates of UROMED Kurt Drews KG can be downloaded from our website:
www.uromed.de under the menu item Service → Certificates

We will be pleased to send you the declarations of conformity in accordance with Directive 93/42/EEC or Regulation (EU) 2017/745 on request.

In its role as distributor, UROMED verifies according to Article 14 of Regulation (EU) 2017/745 that the delivered products are CE marked and that valid EU declarations of conformity are available, that the delivered medical devices are accompanied by the information to be provided by the manufacturer (labelling and instructions for use) and that an UDI has been assigned.

With kind regards

UROMED
Kurt Drews KG
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Thomas Hems, Managing Director
UROMED Kurt Drews KG