KÖGEL HIGH-TECH IN METALL	**EU declaration of conformity Medical devices of risk class I**	Document name: **EU conformity** **Document number: 304513** Form last reviewed on: **13.02.2002 / version: 1**

EU declaration of conformity
for medical devices of risk class I in accordance with Regulation (EU) 2017/745, Annex VIII

We,

Kögel GmbH, registered place of business in D-75038 Oberderdingen, Hagenfeldstraße 4,

declare under our sole responsibility and with legally binding effect that the products and product groups listed below comply with the requirements of Regulation (EU) 2017/745, in particular with the general safety and performance requirements set out in Annex I, and with all applicable and relevant national provisions.

Manufacturer's SRN: DE-MF-000012235

Object of the declaration (product name, ID and basis UDI-DI):

- Wistainer: Article number 22.216.****, basic UDI 42 6067256 100 9M
- Small-parts trays: Article number 22.216.****, basic UDI 42 6067256 200 9S
- Instrument trays: Article number 22.216.****, basic UDI 42 6067256 500 A9
- Endoscopy baskets: Article number 22.216.****, basic UDI 42 6067256 700 AK
- Sterile goods baskets: Article number 28.216.****, basic UDI 42 6067256 750 B2

Purpose:
Our products are used for methodical organization, storage, transport, use and processing of other medical devices.

Determination of the class:
According to Rule 1, Chapter III Non-invasive devices, Annex VIII of Regulation (EU) 2017/745, this is a risk class I medical device. The conformity assessment procedure was carried out in accordance with Article 52(7) of said Regulation.

The following standards were complied with:

- DIN EN ISO 13732-1: 2008-12,
- DIN EN ISO 14971:2022-04,
- DIN EN ISO 10993-1:2021-05,
- DIN EN 10088-3:2014-12,
- DIN 58952-2:2012-04,
- DIN 58952-3:2012-04,
- DIN 58953-8:2019-03,
- ANSI / AAMI ST 77-2013.

Place: Oberderdingen
Date: 28 January 2022

Name: Reinhold Höhne
Function: PRRC

Signature:

Signed for Kögel GmbH and on behalf of the management / quality management