CE Konformitätserklärung / *EC Declaration of Conformity*

Hersteller / *Manufacturer*:	medwork GmbH Medworkring 1 91315 Höchstadt Germany
Produkte / *Products*:	Wiedererwendbare Biopsiezangen - BIO2 - Serie / *Biopsy forceps _ Reusable - BIO2 - series* *(Nicht aktive Medizinprodukte/ Non active medical devices)*
Klassifizierung / Classification:	Risikoklasse / *Risk class*: I Regel / *Rule*: 5
Konformitätsbewertungsverfahren: *Conformity assessment route*:	Anhang VII der Richtlinie 93/42/ EWG geändert durch Richtlinie 2007/47/EG *Annex VII to Council Directive 93/42/EEC amended by Directive 2007/47/EC*

Wir erklären hiermit in alleiniger Verantwortung, dass die oben genannten Produkte den Bestimmungen der Richtlinie 93/42/EWG des Rates über Medizinprodukte entsprechen. Alle Nachweise und Dokumente werden in den Räumlichkeiten des Herstellers aufbewahrt.

We herewith declare under sole responsibility that the above mentioned products meet the provisions of COUNCIL DIRECTIVE 93/42/EEC concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

Angewandte Standards / *Standards applied*:

- *DIN EN ISO 14971:2013-04 Medical devices - Application of risk management to medical devices*
- *DIN EN ISO 10993-1:2010-04 Evaluation and testing within a risk management system*
- *DIN EN ISO 10993-5:2009-10 Tests for in vitro cytotoxicity*
- *DIN EN ISO 10993-7:2009-02 Ethylene oxide sterilization residuals*
- *DIN EN ISO 10993-10:2014-10 Tests for irritation and skin sensitization*
- *DIN EN ISO 10993-17:2009-08 Establishment of allowable limits for leachable substances*
- *DIN EN ISO 7153-1:2017-02 Surgical instruments - Metallic materials - Part 1: Stainless steel*
- *DIN EN 1041:2013-12 Information supplied by the manufacturer of medical devices*
- *DIN EN ISO 15223-1:2017-04 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
- *DIN EN ISO 17664:2018-04 Processing of health care products — Information to be pro-vided by the medical device manufacturer for the processing of medical devices*

CE-Kennzeichnung seit / CE marked since: 11-1998

Anwendungsbereich / *Scope of application*: alle LOT-Nummern /*all lot numbers*

Datum der Ausstellung / *Date of issue:* 2018-06-18

Gültig bis / *Valid until:* 2020-05-25

Volker Schmitt, Safety manager medical products

(Name, Function)

(Signature)

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