Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Ernst Kratz GmbH
Manufacturer address and contact details	Goerzallee 263, 14167 Berlin, Germany
Single Registration Number (SRN) (if available)	DE-MF-000012746

Notified body name (if applicable)	DQS Medizinprodukte GmbH
Notified body number (if applicable)	0297
Directive Certificate number(s) to which this confirmation is made (if applicable)	170775705
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	31 December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Directive Certificate(s) as listed above or in the attached schedule

Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreements are in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

Quality Management System (QMS)

A QMS in accordance with Article 10(9) MDR is in place.

Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Ernst Kratz GmbH

Goerzallee 263

14167 Berlin, Germany

Phone: +49 30 290233500

Email: ernstkratz@acufirm.de

Berlin, 03. September 2024

Silja Kluge

Managing Director / PRRC

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Kanülen, unsteril (cannulas, non-sterile)	170775705	26 May 2024	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	31 December 2028
Wundnadeln, steril (Suture Needles, sterile)	170775705	26 May 2024	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	31 December 2028
Wundnadeln, unsteril (Suture Needles, non-sterile)	170775705	26 May 2024	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	31 December 2028

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Ernst Kratz GmbH

Goerzallee 263
14167 Berlin
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Cannulas, non-sterile	Class IIa
Suture Needles, sterile	Class IIa
Suture Needles, non-sterile	Class IIa

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	526407 MR2
Certificate unique ID	170775705
Effective date	2021-04-03
Expiry date	2024-05-26
Frankfurt am Main	2021-04-03

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.