Declaration of the Manufacturer

With regard to Regulation (EU) 2023/607 of 15 March 2023, 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 regard to

- the validity of certificates issued pursuant to Council Directive 93/42/EEC on medical devices (MDD) (directive certificates) and

- compliance with the requirements for the continued placing on the market and putting into service of the products by us as their manufacturer

name of the manufacturer	KABE-Labortechnik GmbH
address of the manufacturer and contact information	Jägerhofstraße 17 51588 Nümbrecht-Elsenroth, Germany +49 2293 91320 info@kabe-labortechnik.de
EUDAMED single registration number (SRN)	DE-MF-000011861

name of the notified body	TÜV Rheinland LGA Products GmbH
Identification number of the notified body	NB0197
number of the EC certificate 93/42/EEC to which this declaration refers	HD 60150763 0001
original validity date as specified in the directive certificate prior to the extension of its validity	2024-05-26
end date of the extended validity period/transition period	2028-12-31

We as the manufacturer, declare under our sole responsibility:

- that, for the certificate listed above, the conditions for the statutory extension of validity under **Directive 93/42/EEC**, in accordance with Article 120(2) of the MDR (as amended by (EU) 2023/607 of 15 March 2023), are met, and
- that the products listed in the certificate and we, as their manufacturer, meet the conditions set forth in Article 120(3c) of the MDR (as amended by (EU) 2023/607 of 15 March 2023) for their continued placing on the market and putting into service by fulfilling the following requirements:

1. The directive certificate for the listed products was issued after 25 May 2017, was still valid on 26 May 2021, was not subsequently withdrawn, and expires after 20 March 2023.

2. We submitted a formal application for conformity assessment to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII to Regulation (EU) 2017/745 no later than 26 May 2024, for the products listed in Certificate No.: HD 60150763 0001, and the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of the MDR no later than 26 September 2024.

3. This is confirmed by the Notified Body Confirmation Letter,
   Reference: KABEL_PLA0HZ_2024-06-18, order # 1160753

4. A quality management system in accordance with Article 10(9) of Regulation (EU) 2017/745 is demonstrated by the EN ISO 13485:2016 + AC:2018 + A11:2021 certificate, No.: SX 1614112-1

5. The products listed in Certificate 93/42 EEC No. HD 60150763 0001 meet the following conditions:

- The products continue to comply with Directive 93/42/EEC.
- There have been no significant changes to the design or intended purpose.
- The products do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

2026-09-11 _____

André Kolpe (General manager)