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 diagnostics, in particular with regard to

- the validity of the certificates issued in accordance with Council Directive 93/42/EEC on medical devices (MDD) (directive certificates) and
- the compliance with the requirements for the further placing on the market and commissioning of the products and 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 LGS Products GmbH
notified body identification number	NB0197
number of the EC certificate 93/42/EEC which this declaration refers to	HD 60150763 0001
original validity date as stated in the policy certificate prior to the extension of validity	2024-05-26
end date of the extended validity/transition period	2028-12-31

We as the manufacturer declare under our sole responsibility:

- that the conditions for the statutory extension of the validity of the **certificate listed above in accordance with Directive 93/42/EEC** are fulfilled in accordance with article 120.2 of the MDR (as amended by (EU) 2023/607 of 15 March 2023), and
- that the products listed in the certificate and we, as their manufacturer, meet the conditions listed in article 120.3c of the MDR (as amended by (EU) 2023/607 of 15 March 2023) for further placing on the market and putting into service by fulfilling the following requirements:

1. the certificate of conformity for the listed products was issued after 25 May 2017, was valid until 26 May 2021, was not withdrawn thereafter and expires after 20 March 2023

2. a formal application for conformity assessment with the notified body in accordance with section 4.3 subparagraph 1 of Annex VII of Regulation (EU)2017/745 has been submitted by us to a notified body by 26 May 2024 at the latest for the products listed in certificate no.: HD 60150763 0001 and signed written agreements in accordance with section 4.3 subparagraph 2 of Annex VII of the MDR are available before 26 September 2024

3. a quality management system in accordance with (EU)2017/745 article 10 paragraph 9 is verified with certificate EN ISO 13485:2016, No.: SX 1614112-1.

4. the products listed in the certificate 93/42 EEC No.: HD 60150763 0001 fulfil the following conditions:
   - The products continue to comply with Directive 93/42/EEC
   - There are no significant changes to the design and purpose.
   - The products do not pose an unacceptable risk to the health or safety of patients, users or third parties or to aspects of public health protection.

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
51588 Nümbrecht-Elsenroth
Telefon 02293 / 596

2024-08-21 _____

André Kolpe (General manager)