

TO WHOM IT MAY CONCERN

Medolla (Modena), August 02nd, 2023

SUBJECT: declaration of extension of the validity of the CE Certificate MED 23010-A

Hereby, Medica S.p.A. with registered office in via degli Artigiani, 7 – 41036 Medolla (Modena), Manufacturer pursuant to Regulation (EU) 2017/745,

d e c l a r e s

a) to be in the conditions described in Regulation (EU) 2023/607 of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular:

- is in possession of the CE Certificate code MED 23010-A, issued by the Notified Body Kiwa Cermet Italia S.p.A. (id. 0476) according to Directive 93/42 (MDD), expired on 17/03/2023;
- the Medical Devices covered by the Certificate mentioned above all belong to classes: IIb; IIa; I with measuring functions;
- **the validity of the CE Certificate code MED 23010-A, is extended according to Article 1 (Amendments to Article 120 of Regulation (EU) 2017/745) of Regulation (EU) 2023/607, as described below:**

b) paragraph 3 is replaced by the following:

...

3a. Devices which have a certificate issued in accordance with Directive 93/42/EEC ... may be placed on the market or put into service until the following dates:

b) 31 December 2028, for class IIb devices other than those referred to in point (a) of this paragraph, **for class IIa devices and for class I devices** placed on the market under sterility conditions or **with a measuring function**.

- b) that the medical devices listed in the CE Certificate MED 23010-A, issued by Kiwa Cermet Italia (O.N. 0476) pursuant to Directive 94/42/EEC, are still complying with the aforementioned Directive;
- c) that no significant changes have been made in the design and intended use of such medical devices;
- d) that such devices do not show unacceptable risks to the health or safety of patients, users or other persons or to other aspects of public health protection;

- e) that a quality management system is already established in accordance with Article 10(9), as attested by ISO 13485 Certificate No. 3686-M issued by Kiwa Cermet Italia S.p.A.;
- f) that a formal application has already been submitted to Kiwa Cermet Italia (CERBO 0448822 of 10 March 2023, approved by Medica S.p.A. on 15 March 2023) in accordance with the first subparagraph of point 4.3 of Annex VII for the conformity assessment of devices referred to in paragraph 3 bis or 3 ter of Article 1 of Regulation 2023/607, accepted by Kiwa Cermet Italia and Medica S.p.A. as attested in the "Confirmation Letter" dated 2023/08/02.



Dr. Antonio Rossetti
Medica QS/RA Manager