Mirandola, 12/03/2024

Object: **"Legacy" Devices Statement**

We hereby declare that the medical devices manufactured by **HMC Premedical S.p.A.**, covered by CE marking with certificates n° 1668/MDD and 1669/MDD issued by the Notified Body n° 0051 – IMQ S.p.A. and valid until 18/04/2024, comply with Directive 93/42/EEC and subsequent updates.

The medical devices covered by the above Certificates are considered "legacy devices" and benefit from the transitional provisions referred to in Article 120 paragraph 3 of Regulation (EU) 2017/745 which provide, among others, that:

- The devices continue to comply with Directive 93/42/EEC;
- There are no significant changes in the design and intended use;
- The requirements of the Regulation on post-market surveillance, market surveillance, supervision, registration of economic operators and devices are met.

In addition, we confirm that for our medical devices covered by the MDR project:

- The EC Declaration of Conformity was duly issued before 26 May 2021 and continues to be periodically maintained valid as long as the devices remain compliant with the MDD and continue to benefit from the extension provided for by Regulation 2023/607.
- An Application for MDR Certification has been sent or will be sent with the Notified Body n° 0051 IMQ S.p.A. with which a Certification Contract will be signed pursuant to Regulation (EU) 2017/745 (MDR), in full compliance with the terms provided for by the legislation in force (26 May 2024 for the Application for Certification and 26 September 2024 for the Contract).

The fulfilment of all the above conditions allows to take advantage of the extension provided for by Regulation 2023/607 which will keep the MDD Certification valid for these medical devices until 31 December 2028.

**HMC Premedical S.p.A.**
QA & RA Manager / PRRC
Bosetti Danilo