Declaration of conformity for the transitional period in Accordance with Article 120 MDR

Annex to the EC Declaration of Conformity according to Annex VII of Council Directive 93/42/EEC concerning medical devices with regard to the extension of the transitional regulation according to MDR Art. 120 for class Ir devices.

This is to confirm that the declaration of conformity according to Directive 93/42/EEC is still valid. The following requirements for the extension of the transitional regime according to MDR Art. 120 have been fulfilled:

- MDR compliant quality management system has been established
- Formal application for a conformity assessment procedure according to MDR has been submitted to a Notified Body
- A mutually signed written agreement with the Notified Body for the conformity
- assessment procedure according to MDR will have been received by September 26, 2024

Furthermore

- our medical devices continue to comply with Directive 93/42/EEC,
- have no significant changes in design or intended purpose and
- do not pose unacceptable risks to the health and safety of patients and users.

Valid until 31.12.2028 or until the conformity assessment procedure according to MDR is completed and replaced by an MDR Declaration of Conformity.

27.5.24
(Date of Issue)

(General Manager)