

**Declaration on extension of certificate issued as per 93/42/EEC**

The following conformity assessment certificate was issued by the notified body in accordance with the directive 93/42/EEC.

| Certificate number including version | Original validity date on certificate | Name of notified body       | Extended validity date of conformity assessment certificate |
|--------------------------------------|---------------------------------------|-----------------------------|-------------------------------------------------------------|
| 10000422846-PA-NA-DNK Rev 0.0        | 26-May-2024                           | DNV GL Presafe A/S (NB2460) | 31-December-2028                                            |

The above-mentioned EC certificate was issued to Fast Plast A/S, Vilhelmsborgvej 2, 7700, Thisted, Denmark. Kellpo A/S declares full ownership of the products and their certificates as part of the take-over of Fast Plast A/S on 01<sup>st</sup> January 2022 (Ref: Letter dated 1<sup>st</sup> December 2021).

Kellpo A/S confirms the eligibility for the extension of the conformity assessment certificate/s through the regulation (EU) 2023/607 amending the regulations (EU) 2017/745 and (EU) 2017/746. Kellpo A/S declares that:

1. the conformity assessment certificate/s issued under 93/42/EEC has/have not been withdrawn;
2. the devices continue to comply with Directive 93/42/EEC;
3. there are no significant changes in the design and intended purpose;
4. the devices 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;
5. a quality management system in accordance with Article 10(9) of the (EU) 2017/745 is put in place on 26 May 2024
6. a formal application with the notified body DNV GL Presafe A/S in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment for the devices in Annex has been made on 26 May 2024
7. a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII has been signed by the manufacturer and the notified body DNV GL Presafe A/S on 26 September 2024

Thisted, 24 May 2024



Kjeld Pedersen  
Chief Executive Officer (CEO)