



elm-plastic GmbH · Kollenbergstraße 7 · 54647 Dudeldorf · Germany

To whom it may concern

Subj: elm-plastic's CE certificate No. 50809-17-04 from Dekra Certification GmbH and declarations of conformity

According to Regulation 2023/607 Article 1(1)(a), certificates issued by Notified Bodies on or after 25 May 2017 in accordance with EU Medical Devices Directive 93/42/EEC, which were still valid on 26 May 2021 and which have not subsequently been withdrawn, remain valid until after the end of the period indicated on the certificate.

WE DECLARE:

The CE certificate mentioned above was issued under the Directive 93/42/EEC after 25 May 2017 and is still valid on 26 May 2021

AND

The conditions for extension of the validity of the CE certificate under the EU Medical Devices Regulation 2017/745 Article 120 are met in relation to the CE certificate.

From this there is no certification gap to be concerned about in our case, as our certificate has an expiration date of 29th July 2023 and therefore falls under the above mentioned regulation and automatically remains valid until 31st December 2028 or until new MDR certificates are issued earlier.

Also, the issued declarations of conformity from elm-plastic remain valid until further notice.

These are:

- DOC-DPI911-MDD-Rev. 2 - Declaration of Conformity Dosing Pipettes
- DOC-DPI921-MDD-Rev. 1 - Declaration of Conformity Dosing Pipettes (2P)
- DOC-SFP711-MDD-Rev. 1 - Declaration of Conformity Shortform Pipettes
- DOC-MCS611-MDD-Rev. 1 Declaration of Conformity Dosing Cups, Spoons and Trays

Dudeldorf, 2023-06-07

Sascha Moehs

Technical Managing Director, PRRC