

May 3rd, 2022

To whomever it may concern:

Dynabeads HLA Class I/II are Class B products according to IVDR classification. Therefore, according to Regulation (EU) 2022/112, these devices may continue to be placed on the market or put into service based on their self-declared IVDD Declaration of Conformity (DoC) issued prior to May 26, 2022 until May 26, 2027 in compliance with IVD Regulation (EU) 2017/746 with no CE-IVD certificate required.

Currently, CE-IVD certificate for Dynabeads HLA Class I/II products is not available. These products are undergoing IVDR certification at the moment. Based on the Regulation (EU) 2022/112, Dynabeads HLA Class I/II inventory will continue to be placed on the market on IVDD DoC basis and with IVDR certification process ongoing. Upon completion of the certification, CE-IVD certificate under IVD Regulation (EU) 2017/746 will be issued and sent to you.

Sincerely,



Angela Estany

Electronically
signed by:
Angela
Estany
Reason:
Approver of
the GxP
document
Date: Jun 3,
2022 08:44
PDT

Director, Quality and Regulatory Affairs