
European Community Council Directive 98/79/EC

Immucor GTI Diagnostics, Inc. hereby declares that the device(s) listed in the Appendix comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD). The List A and List B devices are in accordance with Annex IV (Full Quality Assurance) of the IVDD. The Self-Declared devices are in accordance with Annex III (EC Declaration of Conformity) of the IVDD.

Standards and Directives used in support of conformance to Directive 98/79/EC:

- EN ISO 13485:2016+A11:2021 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2019 Medical devices – Application of risk management of medical devices
- BS EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices / Corrigendum: Performance evaluation of in vitro diagnostic medical devices
- ISO 23640:2015 In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
- EN 62366-1:2015 Medical Devices-Application of usability engineering to medical devices
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- EN ISO 18113-1:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (Professional Use)

Manufacturer: Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha WI 53186 USA

EC Authorized Representative: Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Straße 32
63303 Dreieich
Germany
Phone: (+49) (0) 6103 80560
Fax: (+49) (0) 6103 8056199

This declaration is issued under the sole responsibility of Immucor GTI Diagnostics, Inc. by:


Leon Lambry
Senior Director, Quality and Regulatory Affairs
Immucor GTI Diagnostics, Inc.
Waukesha, WI USA

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Appendix

List A and List B in vitro diagnostic medical devices in accordance with Annex IV (Full Quality Assurance) of the IVDD

Classification: Annex II, List B

LIFECODES HLA-A SSO Typing Kit (628911)
LIFECODES HLA-A eRES SSO Typing Kit (628913)
LIFECODES HLA-B SSO Typing Kit (628915)
LIFECODES HLA-B eRES SSO Typing Kit (628917)
LIFECODES HLA-DRB1 SSO Typing Kit (628923)
LIFECODES HLA-DRB1 eRES SSO Typing Kit (628925)
LIFECODES HLA-DRB 3,4,5 SSO Typing Kit (628927)
LIFECODES HLA Null Allele SSO Typing Kit (628939)

Classification: Self Certify (Self-Declared), Annex III

Dilution Solution (628515UDI)

Conformity Assessment for Annex IV and Annex II, List B in vitro diagnostic medical devices performed by:

TÜV Rheinland LGA Products GmbH (0197)
Tillystraße 2
90431 Nürnberg
Germany
Phone: +49 (0) 9116555225
Fax: +49 (0) 9116555226