Declaration of Conformity

according to the In Vitro Diagnostic Regulation 2017/746

Manufacturer:

TUD SDN BHD (743476-V)
25, JALAN CH LIGHT INDUSTRIES 2B, KAWASAN PERINDUSTRIAN COLLEGE HEIGHT
71700 MANTIN, NEGERI SEMBILAN, MALAYSIA.

European Representative:
P&J PTE OÜ
Harju Maakond, Kuusalu vald,
Pudisoo Kula, Mannimae/1,
74626 Estonia

EC REP

Medical Device:
Product Name : Specimen Receptacles

IVDD – Classification : IVDR 2017/746 (Class A, Rules 5)

Lot/batches/Serial number, Type, Periods of manufacture :
(Where applicable)
(Refer to Appendix 1 for all products list)

Standard Applied : ISO 13485:2016, ISO 6710:2017, ISO 18113-1:2011, ISO 11137-2:2015, ISO 14971:2019, ISO 11737-2:2009, ISO 14820:2004, ISO 1041:2008, ISO 14644-2:2015, ISO 11607-1:2019, ISO 14644-1:2015

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the European IVDR 2017/746

This declaration of conformity is based on the European In Vitro Diagnostic Regulation 2017/746 (Class A, Rules 5)

This declaration valid until ***30th March 2025.***

Place : Malaysia
Date : 2023/03/31

Name : **ZHU.MJ**
Position : **Company Manager**