

DECLARATION OF CONFORMITY

according to the european standard
EN ISO 13485:2016
and Directive 98/79/EC Annex IV, Article 3

Manufacturer:	Protrans medizinische diagnostische Produkte GmbH
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Product group	Protrans HLA SBT Products
Product	Protrans SBT SSP
EN ISO 13485	SX 1181860-1
Expiry Date	2027-03-15
EC Certificate	HL 1181860-1
Expiry Date	2025-03-15
Classification	HLA Typing Products 16 01 04 01 00 HLA-ABDR Devices of List B Annex II
Notified Body	TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg - Germany

REF	PRODUCT LIST NGS
8811	Protrans N5 LR11 NGS

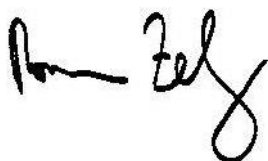
REF	PRODUCT LIST SBT
3401	Protrans S4 HLA-A* Cyclostrip
3301	Protrans S3 HLA-A* Cyclostrip
3402	Protrans S4 HLA-B* Cyclostrip
3302	Protrans S3 HLA-B* Cyclostrip
3403	Protrans S4 HLA-C* Cyclostrip
3303	Protrans S3 HLA-C* Cyclostrip
3404	Protrans S4 HLA-DRB1* Cyclostrip
3304	Protrans S3 HLA-DRB1* Cyclostrip
3204	Protrans S2 HLA-DRB1* Cyclostrip
3309	Protrans S3 HLA-DQB1* Cyclostrip
3208	Protrans S2 HLA-DQA1* Cyclostrip
3211	Protrans S2 HLA-DPB1* Cyclostrip

REF	PRODUCT LIST SBT
54113/64113	Protrans S1 HLA-A*Domino Stones
54215/64215	Protrans S1 HLA-B*Domino Stones
54313/64313	Protrans S1 HLA-C*Domino Stones
54415/64415	Protrans S1 HLA-DRB1*Domino Stones
54416/64416	Protrans S1 HLA-DRB1*Domino Stones
53908/53907	Protrans S1 HLA-DQB1* Domino Stones
51501/61501	Protrans S1 HLA-DRB3* Domino Stones
51601/61601	Protrans S1 HLA-DRB4* Domino Stones
51701/61701	Protrans S1 HLA-DRB5* Domino Stones

REF	PRODUCT LIST SSP
200 070	Protrans HLA-A* Cycloerplate System
200 080	Protrans HLA-B* Cycloerplate System
200 090	Protrans HLA-C* Cycloerplate System
200 030	Protrans HLA-DRB1* Cycloerplate System
201 201	Protrans Negative Control HLA-Class I
200 010	Protrans HLA-A*/B*/C* Cycloerplate System
200 020	Protrans HLA-A*/B*/DRB1* Cycloerplate System
200 040	Protrans HLA-DQB1* Cycloerplate System
200 050	Protrans HLA-DRB1*/DQB1* Cycloerplate System

REF	PRODUCT LIST SSP
200 100 / 105	Protrans Cycloercheck
201 090 / 092	Protrans HPA Domino System
201 093	Protrans HLA Celiac Disease Domino System

We declare under our sole responsibility that above mentioned Product are in compliance with the essential requirements of the Directive **EN ISO 13485:2016** and **Directive 98/79/EC Annex IV, Article 3** for Medical Devices on design, production and sales of HLA tissue typing products and are marked with the **CE-symbol**.



Roman Zelezny
Quality Manager
Hockenheim 23.07.2024



Robert von Drygalski
General Manager