EC Declaration of Conformity (DOC)
IVDR 2017/746/EC

We

Paul Boettger GmbH & Co. KG
Miesleuthenweg 35 - 45
94249 Bodenmais
GERMANY

SRN DE-MF-000022524

Hereby declare as a manufacturer with sole responsibility in the meaning of the regulation, that the following products meet the fundamental requirements of IVDR 2017/746/EC for
In Vitro Diagnostics. The products are designated for skilled personnel for professional use only, and the instruction of use is not necessary. Validity expires by irregular use.

- **Urine Cups and Caps**
- **Stool Containers**

For detailed product list see Appendix 1.
For detailed distributor product list (matrix of assignment) see Appendix 2 (optional).

Jörg Biendl
Qualitätsmanagementbeauftragter (QMB)
Paul Boettger GmbH & Co. KG

Valid till: 06.08.2025

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Appendix 1 – Product List

REF	Description	Class	GMN	Basis UDI
06-013-0100	Urine Cup 125 PP w/o lid, 50 pcs	A	06001IVD	404283606001IVDFN
06-034-0002	Lid Urine PE (red)	A	06001IVD	404283606001IVDFN
06-044-0002	Lid Urine PE w/spout (red)	A	06001IVD	404283606001IVDFN
06-044-0102	Lid Urine PE w/spout (red), 100 pcs	A	06001IVD	404283606001IVDFN
06-044-1002	Urine Cup 125 PP w/lid w/spout (red)	A	06001IVD	404283606001IVDFN
06-044-1102	Urine Cup 125 PP w/lid spout (red), 50/100 pcs	A	06001IVD	404283606001IVDFN
06-053-0100	Urine Cup 100 w/o screw cap, 25 pcs	A	06002IVD	404283606002IVDFV
06-065-0004	Screw Cap Urine 100 (green)	A	06002IVD	404283606002IVDFV
06-065-0104	Screw Cap Urine 100 (green), 100 pcs	A	06002IVD	404283606002IVDFV
06-065-1004	Urine Cup 100 PP w/screw cap (green)	A	06002IVD	404283606002IVDFV
06-065-1104	Urine Cup 100 w/screw cap (green), 25/100 pcs	A	06002IVD	404283606002IVDFV
06-073-1400	Urine Cup 100 PP w/lid (print)	A	06003IVD	404283606003IVDG4
07-011-2001	Tube Stool 22/62 PP w/spoon (blue)	A	07001IVD	404283607001IVDG7
07-011-2101	Tube Stool 22/62 PP w/spoon (blue), 100 pcs	A	07001IVD	404283607001IVDG7
07-023-2007	Tube Stool 20/76 PP scr. cap (brown) w/spoon	A	07001IVD	404283607001IVDG7
07-033-2007	Tube Stool 16/100 PP scr. cap (brown) w/spoon	A	07001IVD	404283607001IVDG7
07-043-2007	Tube Stool 25/107 PP scr. cap (brown) w/spoon	A	07001IVD	404283607001IVDG7
07-043-2107-01	Tube Stool 25/107 PP scr. cap (brown) w/sp., 10 pcs	A	07001IVD	404283607001IVDG7