



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

We

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

SRN DE-MS-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**
- **Sputum 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:** 06.08.2022



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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 |
| 07-061-2000    | Cup Sputum 24 PS w/screw cap (natural), fitted      | A     | 07002IVD | 404283607002IVDGE |



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Appendix 2 – Distributor Product List  
SARSTEDT AG & Co. KG

Matrix of Assignment

SARSTEDT AG & Co. KG (Distributor)

| REF         | Code (D)    | Bezeichnung (D)                 | Description (D)                 |
|-------------|-------------|---------------------------------|---------------------------------|
| 06-013-0100 | 75.1355     | Mehrzweck-Becher 125ml, PP      | Disposable Cup 125ml, PP        |
| 06-034-0002 | 76.1414     | Deckel für 125ml Becher         | Cap for 125ml cup               |
| 06-034-0102 | 76.1414.100 | Deckel für 125ml Becher         | Cap for 125ml cup               |
| 06-044-0002 | 76.1477     | Deckel für 125ml Becher         | Cap for 125ml cup               |
| 06-044-0102 | 76.1477.100 | Deckel für 125ml Becher         | Cap for 125ml cup               |
| 06-065-1004 | 75.1354.010 | Urinbecher 100 ml PP mit Deckel | Urine Cup 100 ml PP w screw cap |