

	ANNEX (AN)	G AN QMI 02.01.01-01 Rev.22
	Medical Products and In Vitro Diagnostic Devices	Seite 1/1 Gültig ab: 21.11.2016

¹⁾ in accordance with EU directive 93/42/EC

²⁾ in accordance with EU directive 98/79/EC

Item-No.	Description	Classification
	Cryo.s™:	IVD²⁾, CE
121 2xx-xxx	Cryo.s™ 2ml, round bottom, w/o Barcode	
122 2xx-xxx	Cryo.s™ 2ml, round bottom, starfoot base, w/o Barcode	
123 2xx-xxx	Cryo.s™ 1ml, conical bottom, w/o Barcode	
124 2xx-xxx	Cryo.s™ 5ml, round bottom, w/o Barcode	
126 2xx-xxx	Cryo.s™ 2ml, round bottom, starfoot base, w/o Barcode	
127 2xx-xxx	Cryo.s™ 4ml, round bottom, starfoot base, w/o Barcode	
	Faeces Container:	IVD²⁾, CE
430 102	Faeces Container (18.5/61 mm)	
431 102	Faeces Container (22/63 mm)	
433 102	Faeces Container (22/63 mm)	
434 102	Faeces Container (41/57 mm)	
443 102	Faeces Container (24.9/90 mm)	
	Sputum Container:	IVD²⁾, CE
432 102	Sputum Container (22/63 mm)	
	ParoCheck® Collection Kit:	MP Class I¹⁾, CE
460 070	ParoCheck® Collection Kit	
	ParoCheck®:	IVD²⁾, CE
460 010	ParoCheck® 10, for 10 samples	
460 110	ParoCheck® 10, for 60 samples	
460 001	ParoCheck® 10, for 1200 samples	
460 020	ParoCheck® 20, for 10 samples	
460 120	ParoCheck® 20, for 60 samples	
460 002	ParoCheck® 20, for 1200 samples	
	PapilloCheck®:	IVD²⁾, CE
465 060	PapilloCheck®, for 60 samples	
465 088	PapilloCheck®, for 288 samples	
	PapilloCheck® high-risk:	IVD²⁾, CE
505 060	PapilloCheck® high-risk, for 60 samples	
	PapilloCheck® Collection Kit:	
465 070	PapilloCheck® Collection Kit	MP Class I¹⁾, CE
465 075	PapilloCheck® Collection Kit	MP Class I¹⁾, CE
862 080	CheckReport™ Software	Active IVD-accessory²⁾
862 070	CheckScanner™	Active IVD-accessory²⁾
515 040	oCheck® DNA Extraction Kit	IVD-accessory²⁾
517 070	oCheck® DNA Extraction Kit - CheckExtractor	IVD-accessory²⁾
517075	Extension Kit for oCheck® DNA Extraction Kit - CheckExtractor	IVD-accessory²⁾
865 070	CheckExtractor™	IVD-accessory²⁾