



EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 116

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Coli O 25:K 11
Anti-Coli O 26:K 60
Anti-Coli O 44:K 74
Anti-Coli O 55:K 59
Anti-Coli O 78:K 80
Anti-Coli O 86:K 61
Anti-Coli O 91:K-
Anti-Coli O 103:K-
Anti-Coli O 111:K 58
Anti-Coli O 114:K 90
Anti-Coli O 118:K-
Anti-Coli O 119:K 69
Anti-Coli O 124:K 72
Anti-Coli O 125:K 70

Anti-Coli O 126:K 71
Anti-Coli O 127:K 63
Anti-Coli O 128:K 67
Anti-Coli O 142:K 86
Anti-Coli O 145:K-
Anti-Coli O 157:K-
Anti-Coli O 158:K-
Anti-Coli O 164:K-
Anti-Coli O 1
Gruber-Widal Serum Anti-Coli O 1
Anti-Coli O 2
Gruber-Widal Serum Anti-Coli O 2
Anti-Coli O 18
Gruber-Widal Serum Anti-Coli O 18

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 18113, DIN EN 13641,
DIN EN 13640, DIN EN 13612, DIN EN ISO 14971,
DIN EN ISO 13485

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2016-12

Berlin, 10.04.2014

Dr. H.-J. Rüger

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer