Certificate BE17/819942643



The management system of

## **Check-Points Health BV**

Binnenhaven 5 6709 PD Wageningen, The Netherlands

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, development, manufacturing and distribution of in vitro diagnostic kits for detection of carbapenemase genes in gramnegative bacteria based on real-time PCR to be used on BD MAX machine.

This certificate is valid from 23/07/2018 until 18/05/2020 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 19/05/2017.

Re certification audit due before 18/04/2020.

Authorised by

Pieter Weterings Certification Manager SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

SGS Belgium 13485-2 0308

Page 1 of 1





Accreditation Number

005-QMS EN ISO/IEC 17021-1:2015





This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.