bsi.

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 577883**

Issued To: **MTC med. Produkte GmbH**
Ampèrestraße 2a
64625 Bensheim
Germany

In respect of:

Design and manufacture of reagents and reagent products for determination of blood groups ABO system, rhesus (C, c, D, E, e) anti-Kell, anti-Duffy and anti-Kidd

Entwicklung und Herstellung von Reagenzien und Reagenzprodukte für die Bestimmung der Blutgruppen ABNull-System, Rhesus (C, c, D, d, E, e), Kell-System, Duffy- und Kidd-System

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

SAO Y BẢN CHÍNH

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

CÔNG TY TRÁCH NHIỆM HỮU HẠN THƯƠNG MẠI-DỊCH VỤ THẠCH PHÁT

GIÁM ĐỐC
LÊ KIM VÂN ANH

Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 July 2016** Date: **09 November 2016** Expiry Date: **01 November 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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