

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**Da An Gene Co., Ltd. of Sun Yat-sen University
19 Xiangshan Road, Science Park
High & New Tech. Development District
510665 Guangzhou, Guangdong
CHINA**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated Feb 05, 2020

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2020-02-05

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MDSS GmbH

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Annex A: Feb 05, 2020
Manufacturer: DA AN GENE CO., LTD. OF SUN YAT-SEN UNIVERSITY

REF	Device Names (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
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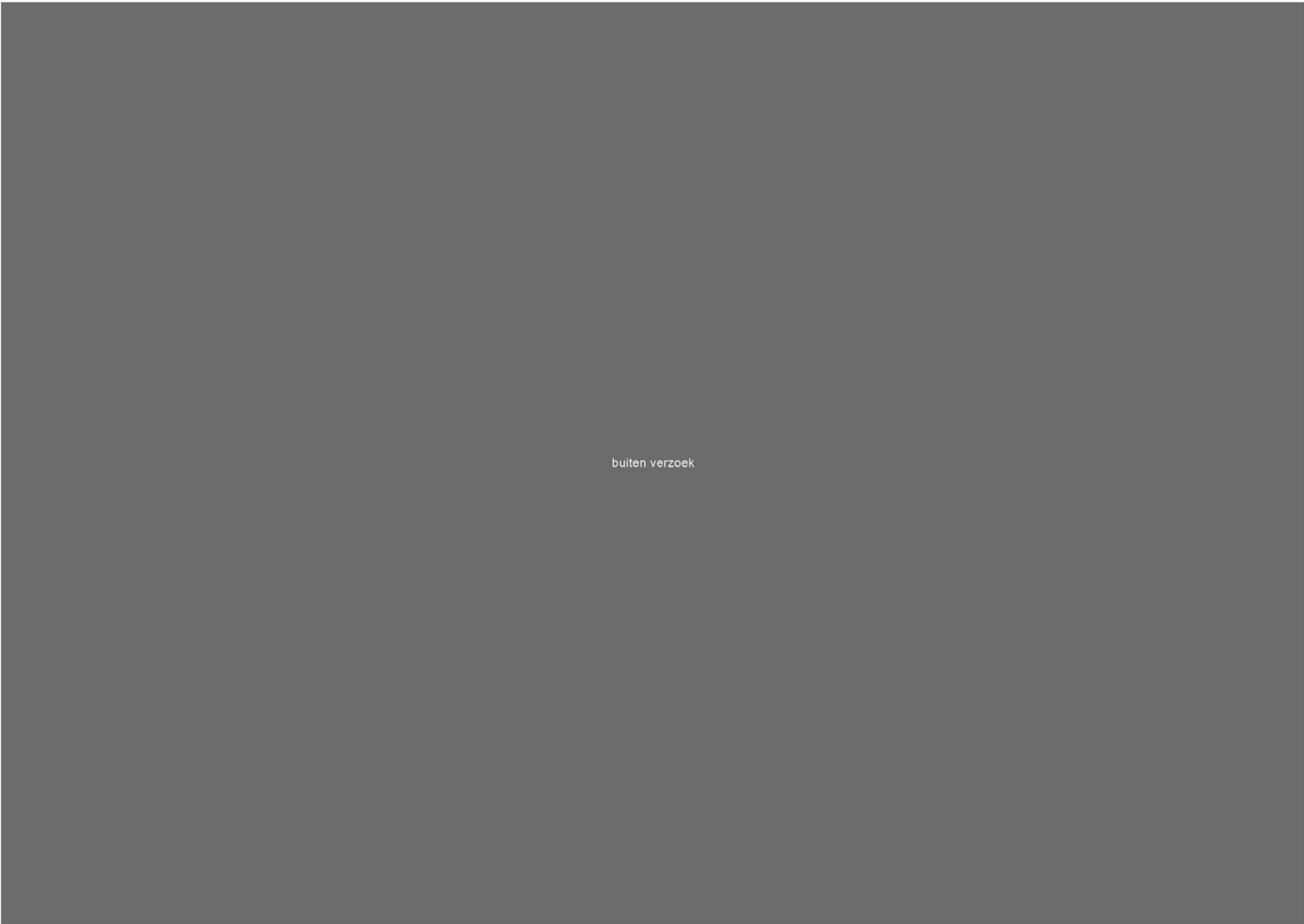
DA-240	Middle East Respiratory Syndrome Coronavirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	15 04 40 19	Coronavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/036
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