



TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
093092	735004370   JA2048276	medical_devices@tuvsud.com	N/A	2024-05-01	1 of 3

## **TÜV SÜD Product Service GmbH Confirmation Letter - Application**

**Reference: 735004370 | JA2048276**

To whom it may concern,

**Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

**SRN Number: JP-MF-000022755**

The devices covered by the formal application mentioned above are identified in the Table below.

**Please note that this letter only confirms the status of the formal application.**

**To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.**

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com).



TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
<2024-05-01>

TÜV SÜD Product Service GmbH  
Medical and Health Services

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<Kazuya Ikemoto>

Conformity Assessment Responsible (CARE)



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**Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR**

Device name or Basic UDI-DI (under MDR application)
<b>Device 1</b> <b>Body Composition Analyzer, DC-240MA</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 2</b> <b>Body Composition Analyzer, MC-980MA-N plus</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 3</b> <b>Body Composition Analyzer, MC-780MA-N</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 4</b> <b>Body Composition Analyzer, DC-430MA</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 5</b> <b>Body Composition Analyzer, SC-240MA</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 6</b> <b>Body Composition Analyzer, MC-980MA</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 7</b> <b>Body Composition Analyzer, MC-780MA</b> <b>Basic UDI-DI : 4904785BCA01RC</b>
<b>Device 7</b> <b>Body Composition Analyzer, MC-580M</b> <b>Basic UDI-DI : 4904785BCA01RC</b>