

TÜV Rheinland LGA Products GmbH • 51105 Köln

Liaoning Upcera Co., Ltd.
No.122 Xianghuai Road, Economic Development Zone, Benxi,
117004 Liaoning,
P.R. China

Contact

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Date September 21, 2023

Notified Body Confirmation Letter

Reference. : 190150449

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Liaoning Upcera Co., Ltd.
No.122 Xianghuai Road, Economic Development Zone, Benxi,
117004 Liaoning,
P.R. China
SRN Number (if available): CN-MF-000013088

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Wenxiang Zhang
Certification body



Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Dental Zirconia Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0068, version A3, Date 2018.03.01) for specifications and models of Dental Zirconia Ceramics, which does not include the newly added specifications and models when applying for MDR. For the newly added specifications and models, please refer to the attachment (File no. UPQ/ZW-32-6356, version A0, Date 2023.09.19) - Differences in Specifications and Models.	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 694138229980HZ			
Device name: Dental Zirconia Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0068, version A3, Date 2018.03.01) for specifications and models of Dental Zirconia Ceramics Basic UDI-DI: 694138229985JB	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Dental Zirconia Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0068, version A3, Date 2018.03.01) for specifications and models of Dental Zirconia Ceramics, which does not include the newly added specifications and models when applying for MDR. For the newly added specifications and models, please refer to the attachment (File no. UPQ/ZW-32-6356, version A0, Date 2023.09.19) - Differences in Specifications and Models. Basic UDI-DI: 694138229986JD	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Dental Lithium Disilicate Glass Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0069, version A2, Date 2017.08.06) for specifications and models of Dental Lithium Disilicate Glass Ceramics, which does not include the newly added specifications and models when applying for MDR.	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
For the newly added specifications and models, please refer to the attachment (File no. UPQ/ZW-32-6357, version A0, Date 2023.09.19) - Differences in Specifications and Models. Basic UDI-DI: 694138229981J3			
Device name: Dental Lithium Disilicate Glass Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0069, version A2, Date 2017.08.06) for specifications and models of Dental Lithium Disilicate Glass Ceramics Basic UDI-DI: 694138229987JF	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Color for the staining of Zirconia Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0070, version A1, Date 2017.08.06) for specifications and models of Color for the staining of Zirconia Ceramics, which does not include the newly added specifications and models when applying for MDR. For the newly added specifications and models, please refer to the attachment (File no. UPQ/ZW-32-6358, version A0, Date 2023.09.19) - Differences in Specifications and Models. Basic UDI-DI: 694138229982J5	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Color for the staining of Zirconia Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0070, version A1, Date 2017.08.06) for specifications and models of Color for the staining of Zirconia Ceramics, which does not include the newly added specifications and models when applying for MDR. For the newly added specifications and models, please refer to the attachment (File no. UPQ/ZW-32-6358, version A0, Date 2023.09.19) - Differences in Specifications and Models. Basic UDI-DI: 694138229988JH	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Color for the staining of Zirconia Ceramics Model: Please refer to the attachment (File no. UPQ/JZ-42-0070, version A1, Date 2017.08.06) for specifications and models of Color for the staining of Zirconia Ceramics, which does not include the newly added specifications and models when applying for MDR. Basic UDI-DI: 694138229989JK	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Dental Filling/Restorative Polymer Based Block Model: Please refer to the attachment (File no. UPQ/JZ-42-0108, version A0, Date 2016.04.18) for specifications and models	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
of Dental Filling/Restorative Polymer Based Block Basic UDI-DI: 694138229983J7			
Device name: Glaze Paste Model: Please refer to the attachment (File no. UPQ/JZ-42-0220, version A0, Date 2018.01.08) for specifications and models of Glaze Paste Basic UDI-DI: 694138229991J6	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Glaze Paste Model: Please refer to the attachment (File no. UPQ/JZ-42-0220, version A0, Date 2018.01.08) for specifications and models of Glaze Paste Basic UDI-DI: 694138229984J9	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197
Device name: Glaze Paste Model: Please refer to the attachment (File no. UPQ/JZ-42-0220, version A0, Date 2018.01.08) for specifications and models of Glaze Paste Basic UDI-DI: 694138229992J8	Class IIa	N/A	Certificate #1:HD601289310001; NB #:0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/21	190150449	Initial issue