DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Micerium S.p.A

Via G.Marconi 83

16036 Avegno

Italien

2023-09-08

Notified Body Confirmation Letter

Reference: 31618257

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 device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

Micerium S.p.A

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SRN: IT-MF-000010187

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a

written agreement concluded, but DQS Medizinprodukte GmbH 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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 the 20 Mar 2023 for the relevant devices.

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:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 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,

i.A. Daniel Siuda

Regulatory Affairs Manager

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 and Basic UDI-DI (as proposed by the manufacturer within the 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
<u>Product File ID</u> **TD1C** **Famiglia 1c Ena Post – Tender Fiber** Model & Type: **Tender Fiber :ORTHO / DUE / QUATTRO / ZERO** **ENA POST: Post conicity 2% and 10%. Drills 2% and 10%** **Basic UDI** **Famiglia 1c TENDER FIBER ORTHO – DUE – QUATTRO** **++EMICFAM1C4U5** **Fam 1c** **ENA POST** **++EMICFAM1C2TZ** **Fam1c** **ENA POST DRILL** **++EMICFAM1C3U3**	Class IIa	**Orthodontics and Dental products:** • Tender Fiber : • Ena Post ENA POST Drill	Certificate G2 18 02 33043 022 (NB #0123)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
Fam 1c **ENA POST KIT: including both post and drills** **++EMICFAM1C2KXT**			
<u>Product File ID</u> **TD1ACEM** **Famiglia 1ACEM** **Products for Aesthetic Restoration: Ena Cem** Model & Type: • **Ena Cem** • **Ena Cem HF** • **Ena Cem Z cement + primer** **Basic UDI** • **FAM1ACEM - 3c EnaCem dual composite for adhesive cementations** **++EMICFAM1ACEM7A** • **FAM1ACEMK - 2b-1a-3c Procedural Kits/ Procedural Kits containing products for luting, including bonding and etching**	Class IIa	**Orthodontics and Dental products:** • Ena Cem • Ena Cem HF • Ena Cem Z cement + primer	Certificate G2 18 02 33043 022 (NB #0123)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
FAM1A - 2b-1a-3c - + FAM1D+5B Procedural Kits containing products for luting, including bonding and etching, and polishing **++EMICFAM1ACEMKL8** • **FAM1ACEM - 2c EnaCem Z Primer for zirconia adhesion** **++EMICFAM1ACEMZP4Y** • **FAM1ACEM - 3d EnaCem Z Self-curing composite cement** **++EMICFAM1ACEMZM6** • **FAM1ACEM - 3d+2c EnaCem Z Self-curing composite cement + Primer**			

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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 zirconia adhesion **++EMICFAM1ACEMZK4N**			
Product File ID **TD. 5: A/B** **Famiglia 5 Rotary Instruments** Model & Type **Ena / Enamel plus SHINY – SMART PROPHY** **Model and type:** **- Ena / Enamel Shiny burs, rubbers, mandrels. brushes, felts** **- Smart Prophy rubbers and brushes** **Basic UDI** • **FAM5A - Ena Shiny diamond burs** **++EMICFAM5AVK** • **Ena Shiny carbide burs** **++EMICFAM5A2UF** • **FAM5B – 4 Smart prophy** **++EMICFAM5B4GYG** • **4b brush Smart Prophy** **++EMICFAM5B4SZ8**	**Class IIa**	**Orthodontics and Dental products:** Ena / Enamel plus SHINY	**Certificate G2 18 02 33043 022 (NB #0123)**

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
• FAM5B - 5b Synthetic brushes 5S felts and goat brushes Ena/Enamel Plus Shiny ++EMICFAM5B5SZB • FAM5B - 5C discs Ena/Enamel Plus Shiny/ Ena/Enamel Plus Shiny/ DISPOSABLE discs ++EMICFAM5B5CYB • FAM5B - 5G Rubbers Ena/Enamel Plus Shiny disposable rubbers ++EMICFAM5B5GYK • FAM5B - 6M Ena/Enamel Plus Shiny/ REUSABLE mandrels ++EMICFAM5B6MZ2 • FAM5B – 5-6 Ena Shiny kits for finishing and polishing including rotary instruments FAM5B-5/6 ++EMICFAM5BKW2			

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
<u>Product File ID</u> **TD1AE** **Famiglia 1AE Products for Aesthetic Restoration: Composite** Model & Type: **Hybrid and flowable composite Ena / Enamel plus** - **Hri: Universal Enamels, Universal Dentine, Intensive enamels** - **HRi Biofunction BF enamel and BD dentine** - **HFO Generic enamel, Universal dentine, Intensive and opalescent enamels, Glass Connector** - **Flow: HFO, HRi, Ena Cem HV, Bulkfill, Stain** - **Ena Flow Sealant** - **Ena Soft and Ena Soft Flow** - **Ena Tender: paste opaque, dentine opaque (Pink, Pink flow**	Class IIa	**Orthodontics and Dental products:** - Hri: Universal Enamels, Universal Dentine, Intensive enamels - HRi Biofunction BF enamel and BD dentine - HFO Generic enamel, Universal dentine, Intensive and opalescent enamels, Glass Connector - Flow: HFO, HRi, Ena Cem HV, Bulkfill, Stain - Ena Flow Sealant - Ena Soft and Ena Soft Flow - Ena Tender: paste opaque, dentine opaque (Pink, Pink flow) - Ena Tender Bond, Ena Etch Silane, Temp Bonding Fluid	Certificate G2 18 02 33043 022 (NB #0123)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
- Ena Tender Bond, Ena Etch Silane, Temp Bonding Fluid **Basic UDI** • FAM1A – 6d1.a Ena Tender Bond **++EMICFAM1ALVD** • FAM1A – 6d1.b Temp Bonding Fluid **++EMICFAM1ALBZA** • FAM1A - 6d1.c Ena Etch Silane **++EMICFAM1ALCZC** • FAM1AE -6d2ENA TENDER **++EMICFAM1AEOZF** • 6a.ENA/Enamel Plus HRI • 6a2a ENA/Enamel Plus HRI • 6a3ENA/Enamel Plus HFO • 6a4ENA/Enamel Plus HRI Bio Function **++EMICFAM1AEUX** • 6b1ENA/Enamel Plus FLOW **++EMICFAM1AE6B1FV**			

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
• **- 6c1 ENA TENDER Dentin Opaque** **++EMICFAM1AE6C1FY** • **6c2 ENA TENDER** **++EMICFAM1AE6C2G2** • **FAM1AE - 6b2 ENA FLOW Sealant Bio** **++EMICFAM1AEB25P** • **FAM1AE - 6bEna Soft Light-** **++EMICFAM1AEB35R** • **FAM1AE – 6 Assorted kits of light curing composite (61a + 61b)** **++EMICFAM1AE6XX**			
<u>Product File ID</u> **TD1 A** **Famiglia 1A Bond Products for Aesthetic Restoration: Bonding system** Model & Type: **Family 1AE.** **1ABOND Bonding system:**	Class IIa	**Orthodontics and Dental products:** - Ena Bond: - Ena Bond SE: primer and resin - Ena Etch	Certificate G2 18 02 33043 022 (NB #0123)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
- **Ena Bond: light curing and catalyst, Ena Seal** - **Ena Bond SE: primer and resin** - **Ena Etch** **Basic UDI** • **FAM1A - 2b1-a+b EnaBond dentine-enamel adhesive system** **++EMICFAM1AV7** • **FAM1A - 2b1-c Ena Bond-Seal** **++EMICFAM1A2B1CD8** • **FAM1A - 2b2 EnaBond SE Adhesive+Primer** **++EMICFAM1A2B22V** • **FAM1ACID - 1an EnaEtch Phosphoric acid between 35% and 38%:** **++EMICFAM1ACID74**			
<u>Product File ID</u> **TD1F** **Famiglia 1f Ena White**	Class IIa	**Orthodontics and Dental products:** -ENA WHITE	Certificate G2 18 02 33043 022 (NB #0123)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
ENA WHITE **Model and type:** **-ENA WHITE POWER,** **ENA WHITE REGULAR** **Basic UDI** • **FAM1F - 1a+1b Ena White System** **++EMICFAM1FVH**			
<u>Product File ID</u> **TD3** Model & Type: **Famiglia 3 Micerium Orthodontics** **Brackets** **Archwires and wires** **Springs** **Elastomeric** **Metal Ligatures** **Palatal Bars** **Ball hook** **Tubes** **Bands** **Spinnaker Accessories** **Basic UDI** • **Beta Titanium nickel free arches and wires.**	Class IIa	**Orthodontics and Dental products:** Orthodontics bands, brackets, tubes, wires, ligatures and elastics	Certificate G2 18 02 33043 022 (NB #0123)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
++EMICFAM3A1A139 • **Nickel free wire for retainer** **++EMICFAM3A1A1WEW** • **Aesthetic Nickel Titanium arches and wires.** **++EMICFAM3A1AENTV4** • **Nickel Titanium arches and wires.** **++EMICFAM3A1ANTHC** • **Titanium nickel wire for retainer** **++EMICFAM3A1ANWHJ** • **Steel arches and wires.** **++EMICFAM3A1AS5B** • **Steel Springs.** **++EMICFAM3A1BXA** • **Nickel Titanium Springs.** **++EMICFAM3A1B13C** • **Metal Ligatures.** **++EMICFAM3A2U5** • **Orthodontic accessories (not for direct bonding**			

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
++EMICFAM3A6UD • **Stainless Steel Bands to be welded with tubes** **++EMICFAM3B3UA** • **Stainless Steel Bands prewelded with tubes** **++EMICFAM3B3AXK** • **Self-legating Stainless steel brackets and tubes (MISTRAL, various models)** **++EMICFAM3C4A1SFZ** • **Standard Stainless steel brackets (VESPER, various models)** **++EMICFAM3C4AS68** • **Direct Bonding Accessories: bottom and cleat** **++EMICFAM3C4CD5G** • **To be welded Accessories: bottom and cleat** **++EMICFAM3C4CW6N**			

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
• Direct Bonding Stainless Steel Orthodontic buccal tubes (SPINNAKER, various models) ++EMICFAM3C4DD5K • Welded Stainless steel Orthodontic buccal tubes (SPINNAKER, various mode ++EMICFAM3C4DW6R • Ceramic brackets (Zephyr) ++EMICFAM3D4BY2 • Ceramic self-ligating brackets (Mistral Klear) ++EMICFAM3D4B14G • Palatal bars ++EMICFAM3E7AYE • Elastic ligature ++EMICFAM3F9BYT • Elastic chains ++EMICFAM3F9CYV • Elastomeric accessories ++EMICFAM3F9DYX			

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
Product File ID **TD. 4** Model & Type: **Ena-Enamel Plus Temp/Temp RESIN** **Powder of different characteristics and colours:** **Liquid for different type of curing** **CAD CAM DISC pre-polymerized acrylic discs.** Basic UDI: • **FAM4 – 4 Ena-Enamel Plus Temp/Temp RESIN** **++EMICFAM439** • **FAM4 - 4.3 ENA TEMP CAD CAM DISC** **++EMICFAM43UN**	Class IIa	**Orthodontics and Dental products** Ena-Enamel Plus	Certificate G2 18 02 33043 022 (NB #0123)

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 and Basic UDI-DI (as proposed by the manufacturer within the 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
09.06.2023	31618257-01	Initial issue
08.09.2023	31618257-02	Addition of all other mentioned Products