

SIORA SURGICALS PRIVATE LIMITED

WZ-1, 2nd Floor, Pool Bagh, Rampura,
110035, New Delhi
India

Date: 23-09-2024

Notified Body Confirmation Letter

Reference: 1000198149

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, 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:

SIORA SURGICALS PRIVATE LIMITED

Registered Site:

WZ-1, 2nd Floor, Pool Bagh, Rampura,
New Delhi – 110035,
India

Manufacturing Site:

1792, HSIIDC Industrial Estate Rai, District, Sonipat,
Haryana – 131029,
India

SRN: IN-MF-000036226

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn,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,

A handwritten signature in blue ink that reads 'Amruta Bhave'.

Amruta Bhave

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
Bone plates and Bone screws System	Class IIb	N/A	0068/QCO-DM/330-2021,Rev 00
Intramedullary Nail System	Class IIb	N/A	0068/QCO-DM/330-2021,Rev 00

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
2024-09-18	1000198149 -1	Initial issue



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/330-2021

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER:

SIORA SURGICALS PRIVATE LIMITED

Registered site: WZ-1, 2nd Floor, Phool Bagh, Ram Pura, New Delhi, 1100335, INDIA

Manufacturing site:

1792, HSIIDC Industrial Estate, RAI, District, Sonipat, Haryana, 131029, INDIA

DEVICE/S:

Bone plate & screws system

MODEL/S:

- | | |
|----------------------------------|----------------------------------|
| ✓ Locking bone plate | ✓ Non-locking bone plate |
| ✓ Locking bone screw | ✓ Non-locking bone screw |
| ✓ LCP-Plate – 2.0 mm | ✓ Locking Plate – Small Fragment |
| ✓ Locking Plate – Large Fragment | ✓ Small Fragment Instrument |
| ✓ Large Fragment | ✓ Mini Fragment Instrument |

list of each single code covered by this certificate is available by the NB

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REVISION Nr.: 00

EXPIRING DATE: 27/05/2024



F-PC-DM-14-01-01 Rev.0.1 en



Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

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Manufacturing site:

1792, HSIIDC Industrial Estate, RAI, District, Sonipat, Haryana, 131029, INDIA

DEVICE/S:

Intramedullary Nail System

MODEL/S:

- | | |
|----------------------------------|--|
| ✓ Femoral interlocking Nail | ✓ Tibial interlocking Nail |
| ✓ Locking bolt and helical blade | ✓ End cap for the interlocking nails |
| ✓ Tibial nail instruments | ✓ Adroit Multifix Tibia Nail Instruments |

list of each model covered by this certificate is available by the NB

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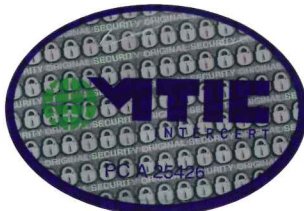
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