Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Star Sports Medicine Co., Ltd.
Rooms A018, B018, Building 1, No.25,
Jinghai 2 Road, Beijing Economic and Technological Development Zone,
100176 Beijing,
P.R. China

Contact

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Mail: medical-products@de.tuv.com

Date November 23, 2023

Notified Body Confirmation Letter
Reference. : CN-MF-000027866

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:

Star Sports Medicine Co., Ltd.
Rooms A018, B018, Building 1, No.25,
Jinghai 2 Road, Beijing Economic and Technological Development Zone,
100176 Beijing,
P.R. China
SRN Number: CN-MF-000027866

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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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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: Metal Suture Anchors **Model:** **TA1A1 TA2A1 TA3A1 TA4A1** **TA1A2 TA2A2 TA3A2 TA4A2** **TA1A3 TA2A3 TA3A3 TA4A3** **TA1B1 TA2B1 TA3B1 TA4B1** **TA1B2 TA2B2 TA3B2 TA4B2** **TA1B3 TA2B3 TA3B3 TA4B3** **TA1C1 TA2C1 TA3C1 TA4C1** **TA1C2 TA2C2 TA3C2 TA4C2** **TA1C3 TA2C3 TA3C3 TA4C3** **Basic UDI-DI:** **697221054CE010000014V**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Metal Suture Anchors **Model:** **TA1HA1 TA2HA1 TA3HA1 TA4HA1** **TA1HA2 TA2HA2 TA3HA2 TA4HA2** **TA1HA3 TA2HA3 TA3HA3 TA4HA3**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; 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
TA1HB1 TA2HB1 TA3HB1 TA4HB1 TA1HB2 TA2HB2 TA3HB2 TA4HB2 TA1HB3 TA2HB3 TA3HB3 TA4HB3 TA1HC1 TA2HC1 TA3HC1 TA4HC1 TA1HC2 TA2HC2 TA3HC2 TA4HC2 TA1HC3 TA2HC3 TA3HC3 TA4HC3 TA1ZA1 TA2ZA1 TA3ZA1 TA4ZA1 TA1ZA2 TA2ZA2 TA3ZA2 TA4ZA2 TA1ZA3 TA2ZA3 TA3ZA3 TA4ZA3 TA1ZB1 TA2ZB1 TA3ZB1 TA4ZB1 TA1ZB2 TA2ZB2 TA3ZB2 TA4ZB2 TA1ZB3 TA2ZB3 TA3ZB3 TA4ZB3 TA1ZC1 TA2ZC1 TA3ZC1 TA4ZC1 TA1ZC2 TA2ZC2 TA3ZC2 TA4ZC2 TA1ZC3 TA2ZC3 TA3ZC3 TA4ZC3 Basic UDI-DI: 697221054CE010000034Z			
Device name: Metal Suture Anchors Model: TA5A1 TA6A1 TA5A2 TA6A2 TA5A3 TA6A3 TA5B1 TA6B1 TA5B2 TA6B2 TA5B3 TA6B3 TA5C1 TA6C1 TA5C2 TA6C2 TA5C3 TA6C3 Basic UDI-DI: 697221054CE010000024X	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Metal Suture Anchors Model: TA5HA1 TA6HA1 TA5HA2 TA6HA2 TA5HA3 TA6HA3 TA5HB1 TA6HB1 TA5HB2 TA6HB2 TA5HB3 TA6HB3 TA5HC1 TA6HC1 TA5HC2 TA6HC2 TA5HC3 TA6HC3 TA5ZA1 TA6ZA1 TA5ZA2 TA6ZA2 TA5ZA3 TA6ZA3 TA5ZB1 TA6ZB1 TA5ZB2 TA6ZB2 TA5ZB3 TA6ZB3 TA5ZC1 TA6ZC1 TA5ZC2 TA6ZC2 TA5ZC3 TA6ZC3 Basic UDI-DI: 697221054CE0100000453	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Non-absorbable Surgical Sutures Model: UHS,UHT Basic UDI-DI: 697221054CE020000015E	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; 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: Non-absorbable Surgical Sutures **Model: UHSN** **Basic UDI-DI: 697221054CE020000025G**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Suture Buttons **Model: EB0F, EB2F, EB3F, EB4F, EB1F, EB1A, EB2A, EB3A, EB4A, EB1J, EB1K** **Basic UDI-DI: 697221054CE030000015X**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Suture Buttons **Model: EB1FI, EB1FII, EB1JI, EB1JII, EB1AI, EB1AII, EB1KI, EB1KII, EB2AI, EB2AII, EB3AI, EB3AII, EB4AI, EB4AII, EB0FI, EB0FII, EB2FI, EB2FII, EB3FI, EB3FII, EB4FI, EB4FII** **Basic UDI-DI: 697221054CE030000025Z**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Suture Buttons **Model: M1M1b0a1, M1N1b0a1, M1O1b0a1, N1N1b0a1, O1O1b0a1,M1M1b0a2, M1N1b0a2, M1O1b0a2, N1N1b0a2, O1O1b0a2, M1M1b0a3, M1N1b0a3, M1O1b0a3, N1N1b0a3, O1O1b0a3, M1S1b0a3, N1S1b0a3, O1S1b0a3, M1T1b0a3, M1U1b0a3, N1T1b0a3, N1U1b0a3, O1T1b0a3, O1U1b0a3, G1P1b2a2, G1Q1b2a2, G1R1b2a2, H1P1b2a2, H1Q1b2a2, H1R1b2a2, I1P1b2a2, I1Q1b2a2, I1R1b2a2, G1V1b2a2, G1W1b2a2, G1X1b2a2, H1V1b2a2, H1W1b2a2, H1X1b2a2, I1V1b2a2, I1W1b2a2, I1X1b2a2, J1P1b0a2, J1Q1b0a2,**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; 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
J1R1b0a2, K1P1b0a2, K1Q1b0a2, K1R1b0a2, L1P1b0a2, L1Q1b0a2, L1R1b0a2, J1V1b0a2, J1W1b0a2, J1X1b0a2, K1V1b0a2, K1W1b0a2, K1X1b0a2, L1V1b0a2, L1W1b0a2, L1X1b0a2,M1M2b0a2, M1N2b0a2, M2N1b0a2, M2O1b0a2, M1O2b0a2, N2N1b0a2, O1O2b0a2, M1M2b0a3, M1N2b0a3, M2N1b0a3, M2O1b0a3, M102b0a3, N2N1b0a3, O1O2b0a3, M1M2b0a4, M1N2b0a4, M2N1b0a4, M2O1b0a4, M102b0a4, N2N1b0a4, O1O2b0a4, S1S1b0c2, S1T1b0c2, S1U1b0c2, T1T1b0c2, U1U1b0c2, S1S1b0d2, S1T1b0d2, S1U1b0d2, T1T1b0d2, U1U1b0d2 **Basic UDI-DI: 697221054CE0300000363**			
Device name: Shaver Blades **Model: Product code: B** **Outer tube: A-O** **Inner tube: 01-20** **Cuteer bar:S,C,T** **Handle: F,S,T** **Models of the product are arbitrary combination of Product code, Outer tube, Inner tube, Cutter bar and Handle** **Basic UDI-DI: 697221054CE040000016G**	Class IIa	N/A	Certificate # HD 2060986-1; NB#0197
Device name: PEEK Suture Anchors **Model: AK1-A1, AK1-A2, AK1-A3, AK1-B1, AK1-B2, AK1-B3, AK2-A1, AK2-A2, AK2-A3, AK2-B1, AK2-B2, AK2-B3,AK3-A1, AK3-A2, AK3-A3, AK3-B1, AK3-B2, AK3-B3, AK9-A1, AK9-A2,**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; 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
AK9-A3, AK9-B1, AK9-B2, AK9-B3, AK10-A1, AK10-A2, AK10-A3, AK10-B1, AK10-B2, AK10-B3, AK2, AK3, AK2-D1, AK2-D2, AK2-D3, AK3-D1, AK3-D2, AK3-D3, AK4-A1, AK4-A2, AK4-A3, AK4-B1, AK4-B2, AK4-B3, AK5-A, AK5-B, AK5-C, AK6-D1, AK6-D2, AK6-D3, AK8-D, AK7-D1, AK7-D2, AK7-D3 **Basic UDI-DI: 697221054CE050000016Z**			
Device name: PEEK Suture Anchors **Model: AKM1A1, AKM1A2, AKM1A3, AKM1B1, AKM1B2, AKM1B3, AKM1D1, AKM1D2, AKM1D3, AKM1E1, AKM1E2, AKM1E3, AKM2A1, AKM2A2, AKM2A3, AKM2B1, AKM2B2, AKM2B3, AKM2D1, AKM2D2, AKM2D3, AKM2E1, AKM2E2, AKM2E3, AKM3A1, AKM3A2, AKM3A3, AKM3B1, AKM3B2, AKM3B3, AKM3D1, AKM3D2, AKM3D3, AKM3E1, AKM3E2, AKM3E3, AKM7A1, AKM7A2, AKM7A3, AKM7B1, AKM7B2, AKM7B3, AKM7D1, AKM7D2, AKM7D3, AKM7E1, AKM7E2, AKM7E3, AKM8A1, AKM8A2, AKM8A3, AKM8B1, AKM8B2, AKM8B3, AKM8D1, AKM8D2, AKM8D3, AKM8E1, AKM8E2, AKM8E3, AKM2, AKM3, AKM4A1, AKM4A2, AKM4A3, AKM4B1, AKM4B2, AKM4B3, AKM4E1, AKM4E2, AKM4E3, AKM5A1, AKM5A2, AKM5A3, AKM5B1, AKM5B2, AKM5B3, AKM5E1, AKM5E2, AKM5E3, AKM6A1, AKM6A2, AKM6A3, AKM6B1, AKM6B2, AKM6B3, AKM6E1, AKM6E2, AKM6E3, AKM9M3A, AKM9M3B, AKM9M3C, AKM9M3E, AKM9P4A, AKM9P4B, AKM9P4C, AKM9P4E, AKM10P1A1, AKM10P1A2, AKM10P1A3, AKM10P1B1, AKM10P1B2, AKM10P1B3,**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; 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
AKM10P1D1, AKM10P1D2, AKM10P1D3, AKM10P1E1, AKM10P1E2, AKM10P1E3, AKM10P2A1, AKM10P2A2, AKM10P2A3, AKM10P2B1, AKM10P2B2, AKM10P2B3, AKM10P2D1, AKM10P2D2, AKM10P2D3, AKM10P2E1, AKM10P2E2, AKM10P2E3, AKM10P5A1, AKM10P5A2, AKM10P5A3, AKM10P5B1, AKM10P5B2, AKM10P5B3, AKM10P5D1, AKM10P5D2, AKM10P5D3, AKM10P5E1, AKM10P5E2, AKM10P5E3, AKM10M3A, AKM10M3B, AKM10M3D, AKM10M3E, AKM10P4A, AKM10P4B, AKM10P4D, AKM10P4E **Basic UDI-DI: 697221054CE0500000273**			
Device name: PEEK Interference Screw Systems **Model: PIS-1, PIS-2, PIS-3** **Basic UDI-DI: 697221054CE060000017J**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: PEEK Interference Screw Systems **Model: PS-1, PS-2, PS-3** **Basic UDI-DI: 697221054CE060000027L**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: PEEK Interference Screw Systems **Model: PSS-1, PSS-2, PSS-3** **Basic UDI-DI: 697221054CE060000037N**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Arthroscopic Shaver Systems **Model: SV-100** **Basic UDI-DI: 697221054CE0700000183**	Class IIa	N/A	Certificate # HD 2060986-1; NB#0197
Device name: All-Suture Anchors	Class IIb excluding Class IIb	N/A	Certificate # HD 2060986-1;

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
Model: AS1A1 AS1A2 AS1A3 AS1B1 AS1B2 AS1B3 AS1C1 AS1C2 AS1C3 AS2A1 AS2A2 AS2A3 AS2B1 AS2B2 AS2B3 AS2C1 AS2C2 AS2C3 AS3A1 AS3A2 AS3A3 AS3B1 AS3B2 AS3B3 AS3C1 AS3C2 AS3C3 AS4A1 AS4A2 AS4A3 AS4B1 AS4B2 AS4B3 AS4C1 AS4C2 AS4C3 AS5A1 AS5A2 AS5A3 AS5B1 AS5B2 AS5B3 AS5C1 AS5C2 AS5C3 **Basic UDI-DI: 697221054CE0900000195**	implantable non-WET		NB#0197
Device name: Meniscal Repair Devices **Model: M01AR, M01BR, M01CR, M01AS, M01BS, M01CS, M01AT, M01BT, M01CT, M02AR, M02BR, M02CR, M02AS, M02BS, M02CS, M02AT, M02BT, M02CT** **Basic UDI-DI: 697221054CE100000014X**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Arthroscopic Access Cannulas ***Model:*** **C11, C12, C13, C14, C15, C16, C17, C18, C19, C110, C111 C21,C22, C23, C24, C25, C26, C27, C28, C29, C210, C211 C31, C32, C33, C34, C35, C36, C37, C38, C39, C310, C311; C41, C42, C43, C44, C45, C46, C47, C48, C49, C410, C411; C51, C52, C53, C54, C55, C56, C57, C58, C59, C510, C511; C61, C62, C63, C64, C65, C66, C67, C68, C69, C610, C611; C71, C72, C73, C74, C75, C76, C77, C78, C79, C710,C711** **Basic UDI-DI: 697221054CE110000015G**	Class IIa	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Arthroscopic Access Cannulas **Model: C0** **Basic UDI-DI: 697221054CE110000025J**	Class IIa	N/A	Certificate # HD 2060986-1; 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: Spiked Ligament Staples **Model: UN I, UN II, UN III, UN IV, UN V, UN VI, UN VII, UN VIII, UN IX, UN X** **Basic UDI-DI: 697221054CE120000015Z**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197
Device name: Spiked Ligament Staples **Model: UN I_R, UN II_R, UN III_R, UN IV_R, UN V_R, UN VI_R, UN VII_R, UN $VIII_R$, UN IX_R, UN X_R** **Basic UDI-DI: 697221054CE1200000365**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2060986-1; NB#0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
2023/11/23	190151201	Initial issue