EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

Star Sports Medicine Co., Ltd.
Room A018, Floor 1, Building 1, NO.25, JingHai 2 Road, Beijing Economic and Technological Development Zone, 100176, BeiJing, China.

EU Authrized Representative:/

Caretechion GmbH
Niederrheinstr 71,40474 Duesseldorf, Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Suture Buttons
Model: see Appendix 1
GMDN Code: 13907, 45062

der Klasse: /
of class: /
de la classe: /
di classe:

IIb, Rule 8 (2.4/1)

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Directive 93/42/EEC Annex II (exclude Sec.4) + Annex VII

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

HD 2060986-1 (issued on 2021-05-25, valid until 2023-12-28)

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Beijing 2021.05.25
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Management representative
Name und Funktion / Name and function /
Nom et fonction / Name e funzione

Appendix 1:

Product model				
EB1F, EB1FI, EB1FII, EBIJ, EB1JI, EB1JII	EB0F, EB0FI, EB0FII	EB2F, EB2FI, EB2FII	EB3F, EB3FI, EB3FII	EB4F, EB4FI, EB4FII
EB1A, EB1AI, EB1AII, EBIK, EBIKI, EB1KII, EB2A, EB2AI, EB2AII, EB3A, EB3AI, EB3AII, EB4A, EB4AI, EB4AII				

Suture Buttons specification table

Suture Button specification/size			
Loop diameter Φ(mm)	Titanium plate Type (1,2,3 Type)		
	Length L x Width W x Thickness D (mm)		
10, 12 or 15-60 (each size interval 5mm) (Only 1 Types)	10-30(each size interval 2mm), 30-50(each size interval 5mm)	3.5-15(each size interval 0.5mm),	1.2-5.1 (each size interval 0.3mm),
	4 Types: Diameter Φ6-30(each size interval 1mm) Thickness D1.2-5.1(each size interval 0.3mm)		

Combined set code			
Single model	Number of Button	Number of Suture with needle	Number of Suture
EB1F(A), EB1FI(B), EB1FII(C), EB1J(D), EB1JI(E), EB1JII(F), EB1A(G), EB1AI(H), EB1AII(I), EB1K(J), EB1KI(K), EB1KII(L), EB0F(M), EB0FI(N), EB0FII(O), EB2F(P), EB2FI(Q), EB2FII(R), EB3F(S), EB3FI(T), EB3FII(U), EB4F(V), EB4FI(W), EB4FII(X), UHS(a), UHSN(b), UHT1(c), UHT2(d)	1；2；3；4	0；1；2；3；4；5；6	0；1；2；3；4

Combined set code	
Combined Type	Model
2 pcs 0 Type Button + 1 pcs UHS	M1M1b0a1, M1N1b0a1, M1O1b0a1, N1N1b0a1, O1O1b0a1
2 pcs 0 Type Button + 2 pcs UHS	M1M1b0a2, M1N1b0a2, M1O1b0a2, N1N1b0a2, O1O1b0a2
2 pcs 0 Type Button + 3 pcs UHS	M1M1b0a3, M1N1b0a3, M1O1b0a3, N1N1b0a3, O1O1b0a3
1 pcs 0 Type Button + 1 pcs 3 Type Button + 3 pcs UHS	M1S1b0a3, N1S1b0a3, O1S1b0a3, M1T1b0a3, M1U1b0a3, N1T1b0a3, N1U1b0a3, O1T1b0a3, O1U1b0a3
1pcs 1 Type Button with adjustable loop + 1pcs 2 Type Buttons + 2pcs UHSN + 2 pcs pulling Suture	G1P1b2a2, G1Q1b2a2, G1R1b2a2, H1P1b2a2, H1Q1b2a2, H1R1b2a2, I1P1b2a2, I1Q1b2a2, I1R1b2a2
1pcs 1 Type Button with adjustable loop + 1 pcs 4 Type Button + 2pcs UHSN + 2pcs pulling Suture	G1V1b2a2, G1W1b2a2, G1X1b2a2, H1V1b2a2, H1W1b2a2, H1X1b2a2, I1V1b2a2, I1W1b2a2, I1X1b2a2
1pcs 1 Type Button with adjustable loop and tail Suture + 1 pcs 2 Type Button + 2pcs pulling Suture	J1P1b0a2, J1Q1b0a2, J1R1b0a2, K1P1b0a2, K1Q1b0a2, K1R1b0a2, L1P1b0a2, L1Q1b0a2, L1R1b0a2
1pcs 1 Type Button with adjustable loop and tail Suture + 1 pcs 4 Type Button + 2pcs pulling Suture	J1V1b0a2, J1W1b0a2, J1X1b0a2, K1V1b0a2, K1W1b0a2, K1X1b0a2, L1V1b0a2, L1W1b0a2, L1X1b0a2
3 pcs 0 Type Button + 2 pcs UHS;	M1M2b0a2, M1N2b0a2, M2N1b0a2, M2O1b0a2, M1O2b0a2, N2N1b0a2, O1O2b0a2
3 pcs 0 Type Button + 3 pcs UHS;	M1M2b0a3, M1N2b0a3, M2N1b0a3, M2O1b0a3, M102b0a3, N2N1b0a3, O1O2b0a3
3 pcs 0 Type Button + 4 pcs UHS;	M1M2b0a4, M1N2b0a4, M2N1b0a4, M2O1b0a4, M102b0a4, N2N1b0a4, O1O2b0a4
2pcs 3 Type Button + 2 pcs flat Suture	S1S1b0c2, S1T1b0c2, S1U1b0c2, T1T1b0c2, U1U1b0c2, S1S1b0d2, S1T1b0d2, S1U1b0d2, T1T1b0d2, U1U1b0d2