



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 19 0466 QS/NB

The quality system of manufacturer

HARDIK INTERNATIONAL PRIVATE LIMITED

Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C., Kalawad Road,
Metoda – 360021, Rajkot, India

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Orthopedic Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2020-12-15
Valid until: 2024-05-27
First Issued: 2019-09-27
Revision: a

Date: 2020-12-15



Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

Product(s):

Name: Bone Screws

Trade name(s): HARDIK®

Model(s):

Ref. No. SS 316L	Ref. No. SS 316LVM	Ref. No. TI-6Al-4V	Item Name	Size	Length	
101	-	T101	Washer	7mm	-	
125	L125	T125		10mm		
201	L201	T201		13mm		
-	-	T001	Cortex Screws	1.5mm	2.0mm to 30mm	
-	-	T025		2.0mm	2.0mm to 50mm	
051	-	T051		2.4mm	2.0mm to 50mm	
076	L076	T076		2.7mm	2.0mm to 80mm	
126	L126	T126		3.5mm	5.0mm to 120mm	
127	L127	T127		3.5mm	5.0mm to 120mm	
202	L202	T202		4.5mm	5.0mm to 150mm	
128	L128	T128		Cancellous Screws (Short Thread)	3.5mm	10.0mm to 150mm
129	L129	T129		Cancellous Screws (Full Thread)	3.5mm	10.0mm to 150mm
130	L130	T130		Cancellous Screws (Short Thread)	4.0mm	10.0mm to 150mm
131	L131	T131	Cancellous Screws (Full Thread)	4.0mm	10.0mm to 150mm	
205	L205	T205	Cancellous Screws (16mm Thread)	6.5mm	10.0mm to 200mm	
206	L206	T206	Cancellous Screws (32mm Thread)	6.5mm	10.0mm to 200mm	
207	L207	T207	Cancellous Screws (Full Thread)	6.5mm	10.0mm to 200mm	

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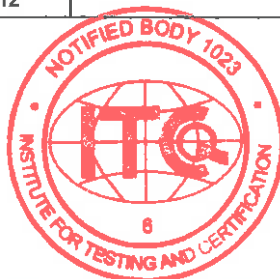
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146	L146	T146	Locking Compression Screws	3.5mm	10.0mm to 150mm
165	L165	T165		2.7mm	10.0mm to 150mm
225	L225	T225		5.0mm	10.0mm to 200mm
147	L147	T147	Locking Cancellous Screw	4.0mm	10.0mm to 160mm
148	L148	T148		4.0mm	10.0mm to 160mm
176	L176	T176		3.5mm	10.0mm to 160mm
177	L177	T177		3.5mm	10.0mm to 160mm
226	L226	T226		6.5mm	10.0mm to 200mm
227	L227	T227		6.5mm	10.0mm to 200mm
228	L228	T228		6.5mm	10.0mm to 200mm
244	L244	T244		5.5mm	10.0mm to 200mm
245	L245	T245		5.5mm	10.0mm to 200mm
246	L246	T246		5.5mm	10.0mm to 200mm
322	L322	T322	Locking Cannulated Screw	6.5mm	10.0mm to 200mm
324	L324	T324		6.5mm	10.0mm to 200mm
325	L325	T325		6.5mm	10.0mm to 200mm
204	L204	T204	Malleolar Screw	4.5mm	20.0mm to 150mm
251	L251	T251	DHS/DCS Lag Screws	-	50.0mm to 150mm
263	L263	T263	Pediatric DHS Screws	-	50.0mm to 150mm
265	L265	T265	Compression Screws	-	20.0mm to 40mm
306	L306	T306	Cannulated Screws	4.0mm	10.0mm to 160mm
307	L307	T307		4.0mm	10.0mm to 160mm
310	L310	T310		6.5mm	10.0mm to 200mm
311	L311	T311		6.5mm	10.0mm to 200mm
312	L312	T312		6.5mm	10.0mm to 200mm

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313	L313	T313	Cannulated Screws	7.0mm	10.0mm to 200mm
314	L314	T314		7.0mm	10.0mm to 200mm
319	L319	T319		7.0mm	10.0mm to 200mm
316	L316	T316	Herbert Screws Cannulated	2.5mm to 4.5mm	12.0mm to 50.0mm
323	-	T323	Suture Anchor Screws	2.5mm to 5.0mm	-
350	L350	T350	Interlocking Bolt	2.9mm	16.0mm to 100mm
351	L351	T351		3.4mm	16.0mm to 100mm
352	L352	T352		3.9mm	16.0mm to 100mm
353	L353	T353		4.9mm	16.0mm to 100mm
354	L354	T354	Hip Locking Bolt	5.0mm to 7.0mm	50.0mm to 160mm
365	L365	T365	Proximal Femoral Neck Screws	6.0mm to 10.0mm	50.0mm to 160mm
414	L414	T414	Cervical Bone Screws	3.5mm to 4.0mm	12.0mm to 50.0mm
415	L415	T415	Cervical Locking Screw	-	-
075	L075	T075	Cortex Screw (Self Tapping)	2.7mm	8.0mm to 150mm
451	L451	T451		3.5mm	8.0mm to 150mm
452	L452	T452		4.5mm	8.0mm to 150mm
478	L478	T478	Schanz Screws	1.5mm to 7.0mm	75.0mm to 300mm
479	L479	T479		1.5mm to 7.0mm	75.0mm to 300mm
480	L480	T480		1.5mm to 7.0mm	75.0mm to 300mm
481	L481	T481		1.5mm to 7.0mm	75.0mm to 300mm
482	L482	T482		1.5mm to 7.0mm	75.0mm to 300mm
483	L483	T483		1.5mm to 7.0mm	75.0mm to 300mm
198	L198	T198	Locking Compression Screws Star Head	2.4mm	8mm to 70mm
199	L199	T199		2.7mm	8mm to 80mm
200	L200	T200		3.5mm	8mm to 100mm
395	L395	T395	PEN-2 Blade Screw 75mm	-	50mm to 150mm

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-	-	T012	Cortical Screw (Self Tapping) (Cross Head)	1.5mm	4mm to 50mm
-	-	T024		2.0mm	4mm to 50mm
-	-	T502	Locking Cortex Screws	1.5mm	4mm to 50mm
-	-	T532		2.0mm	4mm to 50mm
-	-	T562		2.4mm	4mm to 50mm
-	-	T503	Locking Cortex Screw (Self Tapping) (Cross Head)	1.5mm	4mm to 50mm
-	-	T533		2.0mm	4mm to 50mm
-	-	T563		2.4mm	4mm to 50mm

Class: IIB
GMDN: 56642

Name: Bone Pins, Wires & Staples

Trade name(s): HARDIK®

Model(s):

Ref. No. SS 316L	Ref. No. SS 316LVM	Ref. No. Ti-6Al-4V	Item Name	Size	Length
326	-	T326	Stainless Steel Wire Spool	14swg to 32swg	-
327	-	T327	Cerclage Wire with Eye	0.8mm to 2.0mm	150mm to 600mm
328	L328	T328	Kirschner Wire (K Wire) (Double Side Trocar Tip)	0.8mm to 5.0mm	100mm to 300mm
329	L329	T329	Kirschner Wire (K Wire) (Single Trocar Tip)	0.8mm to 5.0mm	100mm to 300mm
330	L330	T330	Kirschner Wire (K Wire) Thread	0.8mm to 5.0mm	100mm to 300mm
334	L334	T334	Coventry Staples	Small, Medium, Large	-
335	L335	T335	U-Staples	1.5mm to 3.0mm	10.0mm to 50mm

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336	-	T336	Ligament Staple	1.5mm to 3.0mm	10.0mm to 50mm
476	L476	T476	Steinman Pin	1.5mm to 6.0mm	125mm to 300mm
477	L477	T477	Steinman Pin (Central Threaded)	2.0mm to 6.0mm	125mm to 300mm

Class: IIb
GMDN: 35685 & 61691


Name: Bone Plates
Trade name(s): HARDIK®

Model(s):

Ref. No. SS 316L	Ref. No. SS 316LVM	Ref. No. Ti-6Al-4V	Item Name	Size	Length
002	-	T002	Mandible Plate with Center Space	1.5mm	2hole to 20hole
026	-	T026		2.0mm	2hole to 20hole
052	-	T052		2.4mm	2hole to 20hole
003	-	T003	Mandible Plate	1.5mm	2hole to 20hole
027	-	T027		2.0mm	2hole to 20hole
053	-	T053		2.4mm	2hole to 20hole
004	-	T004	Orbital Plate with Centre Space	1.5mm	2hole to 20hole
028	-	T028		2.0mm	2hole to 20hole
054	-	T054		2.4mm	2hole to 20hole
005	-	T005	Orbital Plate	1.5mm	2hole to 20hole
029	-	T029		2.0mm	2hole to 20hole
064	-	T064		2.4mm	2hole to 20hole

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006	-	T006	L Plate Angle 2hole	1.5mm	2hole to 10hole
030	-	T030		2.0mm	2hole to 10hole
055	-	T055		2.4mm	2hole to 10hole
103	L103	T103		2.7mm	2hole to 10hole
007	-	T007	L Plate Angle 3hole	1.5mm	2hole to 10hole
031	-	T031		2.0mm	2hole to 10hole
008	-	T008	T Plate Head 2hole	1.5mm	2hole to 10hole
032	-	T032		2.0mm	2hole to 10hole
056	-	T056		2.4mm	2hole to 10hole
104	L104	T104		2.7mm	2hole to 10hole
009	-	T009	X Plate	1.5mm	2hole to 10hole
036	-	T036		2.0mm	2hole to 10hole
057	-	T057		2.4mm	2hole to 10hole
010	-	T010	Y Plate	1.5mm	2hole to 10hole
037	-	T037		2.0mm	2hole to 10hole
058	-	T058		2.4mm	2hole to 10hole
038	-	T038	Double End Y Plate	2.0mm	2hole to 10hole
059	-	T059		2.4mm	2hole to 10hole
039	-	T039	Z Plate	2.0mm	2hole to 10hole
060	-	T060		2.4mm	2hole to 10hole
145	L145	T145	Reconstruction Plate Round Hole	3.5mm	2hole to 30hole
484	L484	T484		4.5mm	2hole to 30hole

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062	-	T062	Reconstruction Plate Angled Round Hole	2.4mm	2hole to 30hole
063	-	T063	Reconstruction Plate Mandible Shape Round Hole	2.4mm	2hole to 50hole
078	L078	T078	DCP Plate	2.7mm	2hole to 30hole
135	L135	T135		3.5mm	2hole to 30hole
210	L210	T210		4.5mm	2hole to 30hole
213	L213	T213		4.5mm	2hole to 30hole
102	L102	T102	Quarter Tubular Plate	2.7mm	2hole to 20hole
133	L133	T133	One - Third Tubular Plate	3.5mm	2hole to 30hole
136	L136	T136	LC-DCP Plate	3.5mm	2hole to 30hole
211	L211	T211		4.5mm	2hole to 30hole
214	L214	T214		4.5mm	2hole to 30hole
137	L137	T137	T - Ellis Plate	2.7mm to 3.5mm	2hole to 14hole
138	L138	T138	T Plate, Right Angled	3.5mm	2hole to 14hole
139	L139	T139	T Plate, Oblique Angled	3.5mm	2hole to 14hole
140	L140	T140	Small T Plate, Right Angled (Head 4 hole)	2.7mm to 3.5mm	2hole to 14hole
061	L061	T061	Reconstruction Plate Straight (DC Hole)	2.4mm	2hole to 30hole
077	L077	T077		2.7mm	2hole to 30hole
141	L141	T141		3.5mm	2hole to 30hole
224	L224	T224		4.5mm	2hole to 30hole
484	L484	T484		4.5mm	2hole to 30hole

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142	L142	T142	Hook Plate	3.5mm	2hole to 30hole
223	L223	T223		4.5mm	2hole to 30hole
143	L143	T143	Cloverleaf Plate	3.5mm to 4.5mm	2hole to 20hole
144	L144	T144	Calcaneal Plate	3.5mm to 4.5mm	Small, Medium, Large
185	L185	T185	Superior Anterior Clavicle Plate	2.7mm to 5.0mm	2hole to 30hole
172	L172	T172	Locking Proximal Radius Neck Plate	2.7mm to 3.5mm	2hole to 14hole
173	L173	T173	Locking Proximal Radius Rim Plate	2.7mm to 3.5mm	2hole to 14hole
149	L149	T149	Locking Compression Plate	3.5mm	2hole to 30hole
229	L229	T229		4.5mm/5.0mm	2hole to 30hole
230	L230	T230		4.5mm/5.0mm	2hole to 30hole
150	L150	T150	Locking Compression T Plate, Right Angled	2.7mm to 5.0mm	2hole to 20hole
151	L151	T151	Locking Compression T Plate, Oblique Angled	2.7mm to 5.0mm	2hole to 20hole
200	L200	T200	Locking Compression T Plate, Oblique Angled head 4Hole	2.7mm to 5.0mm	2hole to 20hole
153	L153	T153	Locking Proximal Humeral Plate	2.7mm to 5.0mm	2hole to 30hole
154	L154	T154	Locking Medial Distal Tibial Plate	2.7mm to 5.0mm	2hole to 30hole
155	L155	T155	Locking Cloverleaf Plate	2.7mm to 5.0mm	2hole to 30hole
156	L156	T156	Locking Long Head Proximal Humeral Plate	2.7mm to 5.0mm	2hole to 30hole
157	L157	T157	Locking Distal Humeral Plate with Support	2.7mm to 5.0mm	2hole to 30hole
158	L158	T158	Locking Distal Humeral Plate	2.7mm to 5.0mm	2hole to 30hole
159	L159	T159	Locking Medial Distal Humeral Plate	2.7mm to 5.0mm	2hole to 30hole

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Paul Vaj
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160	L160	T160	Locking Superior Anterior Clavicle Plate	2.7mm to 5.0mm	2hole to 30hole
161	L161	T161	Locking Superior Anterior Clavicle Plate with Lateral Extension	2.7mm to 5.0mm	2hole to 30hole
163	L163	T163	Locking Medial Distal Tibia Plate without tab	2.7mm to 5.0mm	2hole to 30hole
164	L164	T164	Locking Hook Plate	2.7mm to 5.0mm	2hole to 10hole
166	L166	T166	Locking Volar Distal Radius Plate	2.7mm to 5.0mm	2hole to 10hole
168	L168	T168	Locking XVA Volar Distal Radius Plate	2.7mm to 5.0mm	2hole to 10hole
169	L169	T169	Locking Distal Ulna Plate	2.7mm to 5.0mm	2hole to 10hole
170	L170	T170	Locking Ulna Osteotomy	2.7mm to 5.0mm	2hole to 10hole
167	L167	T167	Locking Calcaneal Plate	2.7mm to 5.0mm	2hole to 10hole
178	L178	T178	Locking One - Third Tubular Plate	2.7mm to 4.5mm	2hole to 30hole
179	L179	T179	Locking Distal Radius Plate	2.4mm to 3.5mm	2hole to 15hole
180	L180	T180	Locking XVA Distal Radius Plate	2.4mm to 3.5mm	2hole to 15hole
175	L175	T175	Locking Distal Fibula Plate	2.4mm to 3.5mm	2hole to 15hole
269	L269	T269	Trochanter Stabilization Plate For DHS	—	138mm to 148mm
162	L162	T162	Locking Clavicle Hook Plate	Hook Depth 12mm to 25mm	3hole to 10hole
247	L247	T247	Locking Anterior Ankle	4.5mm	3hole to 10hole
174	L174	T174	Locking Anterolateral Distal Tibia Plate	2.4mm to 5.0mm	4hole to 25hole
181	L181	T181	Locking XLP Proximal Humeral Plate	3.5mm	2hole to 20hole
182	L182	T182	Locking Posterior Medial Proximal Tibia Plate	3.5mm	2hole to 20hole
183	L183	T183	Locking Proximal Radius Plate	2.4mm to 3.5mm	2hole to 8hole

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171	L171	T171	Locking Olecranon Plate	2.4mm to 3.5mm	2hole to 20hole
243	L243	T243	Locking TomoFix Plate	3.5mm to 5.0mm	2hole to 20hole
208	L208	T208	Semi Tubular Plate	3.5mm to 4.5mm	2hole to 30hole
216	L216	T216	T Plate	4.5mm	2hole to 30hole
215	L215	T215	T Buttress Plate	4.5mm	2hole to 30hole
217	L217	T217	L Buttress Plate	4.5mm	2hole to 30hole
218	L218	T218	L Plate	4.5mm	2hole to 30hole
219	L219	T219	Spoon Plate	4.5mm	2hole to 10hole
220	L220	T220	Lateral Tibial Head Buttress Plate	4.5mm	2hole to 30hole
221	L221	T221	Condylar Buttress Plate	4.5mm	2hole to 30hole
222	L222	T222	Cobra Head Plate	4.5mm	2hole to 30hole
152	L152	T152	Locking Reconstruction Plate	3.5mm	2hole to 30hole
231	L231	T231		4.5mm	2hole to 30hole
232	L232	T232	Locking L-Buttress Plate	3.5mm to 5.0mm	2hole to 30hole
233	L233	T233	Locking T-Buttress Plate	3.5mm to 5.0mm	2hole to 30hole
234	L234	T234	Locking T- Plate	3.5mm to 5.0mm	2hole to 30hole
235	L235	T235	Locking Lateral Tibia Plate	3.5mm to 5.0mm	2hole to 30hole
236	L236	T236	Locking Proximal Tibial Plate	3.5mm to 5.0mm	2hole to 30hole
237	L237	T237	Locking Distal Femoral Plate	3.5mm to 5.0mm	2hole to 30hole
238	L238	T238	Locking Condylar Buttress Plate	3.5mm to 5.0mm	2hole to 30hole
239	L239	T239	Locking Proximal Femoral Plate	3.5mm to 5.0mm	2hole to 30hole

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241	L241	T241	Locking Metaphyseal Plate	3.5mm/4.5mm/5.0mm	2hole to 30hole
184	L184	T184	Locking Medial Proximal Tibial Plate	3.5mm to 5.0mm	2hole to 30hole
261	L261	T261	Locking DHS Plate 38mm Barrel	120° to 150°	2hole to 30hole
262	L262	T262	Locking DHS Plate 25mm Barrel	120° to 150°	2hole to 30hole
270	L270	T270	Locking 95° DCS Plate	95°	2hole to 30hole
252	L252	T252	DHS Plate (DC Hole) 38mm Barrel	120° to 150°	2hole to 30hole
253	L253	T253	DHS Plate (DC Hole) 32mm Barrel	120° to 150°	2hole to 30hole
254	L254	T254	DHS Plate (DC Hole) 25mm Barrel	120° to 150°	2hole to 30hole
255	L255	T255	DCS 95° Plate (DC Hole)	95°	2hole to 30hole
264	L264	T264	Pediatric DHS Plate (DC Hole)	120° to 150°	2hole to 30hole
257	L257	T257	DHS Plate (Round Hole) 38mm Barrel	120° to 150°	2hole to 30hole
258	L258	T258	DHS Plate (Round Hole) 32mm Barrel	120° to 150°	2hole to 30hole
259	L259	T259	DHS Plate (Round Hole) 25mm Barrel	120° to 150°	2hole to 30hole
260	L260	T260	DCS 95° Plate (Round Hole)	95°	2hole to 30hole
266	L266	T266	95° Condylar Plate (DC Hole)	Blade 50mm to 90mm	2hole to 30hole
267	L267	T267	130° Angle Blade Plate (D.C. Hole)	Blade 50mm to 90mm	2hole to 30hole
268	L268	T268	95° Angle Blade Plate (Round Hole)	Blade 50mm to 90mm	2hole to 30hole
453	L453	T453	Pelvic Reconstruction Plate	2.7mm to 4.5mm	2hole to 30hole
-	-	T011	Titanium Mesh	1.5mm	40mm to 300mm
-	-	T040		2.0mm	40mm to 300mm

Date: 2020-12-15
Revision: a



Mgr. Jiří Heš

Mgr. Jiří Heš
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic


Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

187	L187	T187	Locking Distal Radius Plate	2.7mm	2hole to 6hole
188	L188	T188	Locking Distal Radius Buttress Plate (Head 5hole)	2.7mm	2hole to 6hole
189	L189	T189	Locking Distal Radius Plate Extra Articular (Head 5hole)	2.7mm	2hole to 6hole
190	L190	T190	Locking Distal Radius Plate Extra Articular (Head 4hole)	2.7mm	2hole to 6hole
191	L191	T191	Locking Distal Radius Plate Straight	2.7mm	2hole to 6hole
192	L192	T192	Locking Distal Radius L Plate (Head 2hole)	2.7mm	2hole to 6hole
193	L193	T193	Locking Distal Radius L Plate (Head 3hole)	2.7mm	2hole to 6hole
194	L194	T194	Locking Distal Radius L Plate Oblique Angled (Head 3hole)	2.7mm	2hole to 6hole
195	L195	T195	Locking Distal Radius T Plate (Head 3hole)	2.7mm	2hole to 6hole
196	L196	T196	Locking Anatomical Proximal Tibia Plate	3.5mm	2hole to 18hole
197	L197	T197	Locking Proximal Tibia Plate	3.5mm	2hole to 18hole
-	-	T013	Curved Plate	1.5mm	2hole to 10hole
-	-	T041		2.0mm	2hole to 10hole
-	-	T064		2.4mm	2hole to 10hole
-	-	T014	L Plate Angle (Without Bar)	1.5mm	2hole to 10hole
-	-	T042		2.0mm	2hole to 10hole
-	-	T015	Angular Plate	1.5mm	2hole to 10hole
-	-	T043		2.0mm	2hole to 10hole
-	-	T065		2.4mm	2hole to 10hole

Date: 2020-12-15
Revision: a




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Kalawad Road, Metoda – 360021, Rajkot, India

-	-	T017	L Shape 120° Oblique Angled Plate	1.5mm	2hole to 10hole
-	-	T045		2.0mm	2hole to 10hole
-	-	T067		2.4mm	2hole to 10hole
-	-	T018	Nose "Y" Shape Plate	1.5mm	2hole to 10hole
-	-	T046		2.0mm	2hole to 10hole
-	-	T068		2.4mm	2hole to 10hole
-	-	T019	Nose "H" Shape Plate	1.5mm	2hole to 10hole
-	-	T047		2.0mm	2hole to 10hole
-	-	T069		2.4mm	2hole to 10hole
-	-	T020	Chin Plate	1.5mm	2hole to 10hole
-	-	T048		2.0mm	2hole to 10hole
-	-	T070		2.4mm	2hole to 10hole
-	-	T021	Plate	1.5mm	2hole to 10hole
-	-	T049		2.0mm	2hole to 10hole
-	-	T071		2.4mm	2hole to 10hole
-	-	T022	3D Plate	1.5mm	2hole to 10hole
-	-	T050		2.0mm	2hole to 10hole
-	-	T072		2.4mm	2hole to 10hole
-	-	T504	Locking Mandible Plate with Center Space	1.5mm	2hole to 20hole
-	-	T534		2.0mm	2hole to 20hole
-	-	T564		2.4mm	2hole to 20hole

Date: 2020-12-15
 Revision: a



Jiří Heš
 Mgr. Jiří Heš
 Representative of the Notified Body No. 1023



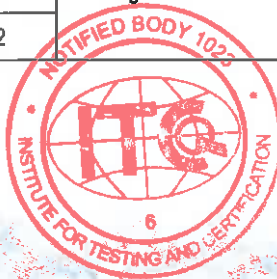
Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

-	-	T505	Locking Mandible Plate	1.5mm	2hole to 20hole
-	-	T535		2.0mm	2hole to 20hole
-	-	T565		2.4mm	2hole to 20hole
-	-	T506	Locking Orbital Plate with Centre Space	1.5mm	2hole to 20hole
-	-	T536		2.0mm	2hole to 20hole
-	-	T566		2.4mm	2hole to 20hole
-	-	T507	Locking Orbital Plate	1.5mm	2hole to 20hole
-	-	T537		2.0mm	2hole to 20hole
-	-	T508	Locking L Plate Angle 2	1.5mm	2hole to 10hole
-	-	T538		2.0mm	2hole to 10hole
-	-	T568		2.4mm	2hole to 10hole
-	-	T509	Locking L Plate Angle 3	1.5mm	2hole to 10hole
-	-	T539		2.0mm	2hole to 10hole
-	-	T510	Locking T Plate Head 2	1.5mm	2hole to 10hole
-	-	T540		2.0mm	2hole to 10hole
-	-	T570		2.4mm	2hole to 10hole
-	-	T511	Locking X Plate	1.5mm	2hole to 10hole
-	-	T541		2.0mm	2hole to 10hole
-	-	T571		2.4mm	2hole to 10hole
-	-	T512	Locking Y Plate	1.5mm	2hole to 10hole
-	-	T542		2.0mm	2hole to 10hole
-	-	T572		2.4mm	2hole to 10hole

Date: 2020-12-15
Revision: a



Mgr. Jiří Heš
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Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

-	-	T515	Locking 3D Plate	1.5mm	2hole to 10hole
-	-	T545		2.0mm	2hole to 10hole
-	-	T575		2.4mm	2hole to 10hole
-	-	T516	Locking Curved Plate	1.5mm	2hole to 10hole
-	-	T546		2.0mm	2hole to 10hole
-	-	T576		2.4mm	2hole to 10hole
-	-	T517	Locking 1.5mm L Plate Angled 2 (Without Bar)	1.5mm	2hole to 10hole
-	-	T547		2.0mm	2hole to 10hole
-	-	T518	Locking Angular Plate 150°	1.5mm	2hole to 10hole
-	-	T548		2.0mm	2hole to 10hole
-	-	T578		2.4mm	2hole to 10hole
-	-	T519	Locking 1.5mm L Plate Angled 3 (Without Bar)	1.5mm	2hole to 10hole
-	-	T549		2.0mm	2hole to 10hole
-	-	T520	Locking "L" Shape 120° oblique Angle Plate	1.5mm	2hole to 10hole
-	-	T550		2.0mm	2hole to 10hole
-	-	T580		2.4mm	2hole to 10hole
-	-	T521	Locking Nose "Y" Shape Plate	1.5mm	2hole to 10hole
-	-	T551		2.0mm	2hole to 10hole
-	-	T581		2.4mm	2hole to 10hole
-	-	T522	Locking Nose "H" Shape Plate	1.5mm	2hole to 10hole
-	-	T552		2.0mm	2hole to 10hole
-	-	T582		2.4mm	2hole to 10hole

Date: 2020-12-15
Revision: a



Mgr. Jiří Heš *J. Heš*
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

-	-	T523	Locking Chin Plate	1.5mm	2hole to 10hole
-	-	T553		2.0mm	2hole to 10hole
-	-	T583		2.4mm	2hole to 10hole
-	-	T524	Locking I Plate	1.5mm	2hole to 10hole
-	-	T554		2.0mm	2hole to 10hole
-	-	T584		2.4mm	2hole to 10hole
-	-	T526	Locking Titanium Mesh	1.5mm	40mm to 300mm
-	-	T556		2.0mm	40mm to 300mm
-	-	T543	Locking Double End Y Plate	2.0mm	2hole to 10hole
-	-	T573		2.4mm	2hole to 10hole
-	-	T544	Locking Z Plate	2.0mm	2hole to 10hole
-	-	T574		2.4mm	2hole to 10hole
-	-	T585	Locking TMJ Plate	2.4mm	2hole to 10hole
-	-	T586	Locking Angled Reconstruction Plate	2.4mm	2hole to 20hole

Class: IIB
GMDN: 61573

Name: Bone Nails

Trade name(s): HARDIK®

Model(s):

Ref. No. SS 316L	Ref. No. SS 316LVM	Ref. No. Ti-6Al-4V	Item Name	Size	Length
356	-	T356	Universal Interlocking Tibial Nail	8.0mm to 14mm	260mm to 500mm

Date: 2020-12-15
Revision: a



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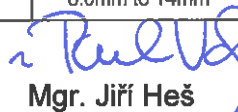
Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

357	-	T357	Universal Interlocking Femoral Nail	8.0mm to 14mm	260mm to 500mm
358	L358	T358	XL Interlocking Tibial Nail	8.0mm to 14mm	260mm to 500mm
359	L359	T359	XL Interlocking Femoral Nail	8.0mm to 14mm	260mm to 500mm
369	L369	T369	XL Interlocking Tibial Nail (Distal Tip)	8.0mm to 14mm	260mm to 500mm
360	L360	T360	Reconstruction Femoral Nail	8.0mm to 14mm	260mm to 540mm
362	L362	T362	Supra Condylar Nail	8.0mm to 14mm	150mm to 300mm
363	L363	T363	Humeral Nail	5.0mm to 10mm	100mm to 500mm
364	L364	T364	Proximal Femoral Nail	8.0mm to 14mm	150mm to 300mm
361	L361	T361	Long Proximal Femoral Nail	8.0mm to 14mm	260mm to 540mm
366	-	T366	Enders Nail	3.5mm	150mm to 500mm
367	-	T367		4.5mm	150mm to 500mm
368	-	T368	K Nail	5.0mm to 16mm	200mm to 600mm
371	L371	T371	Rush Nail	1.5mm to 8.0mm	100mm to 500mm
372	L372	T372	Square Nail Radius	1.5mm to 5.0mm	100mm to 500mm
373	L373	T373	Square Nail Ulna	1.5mm to 5.0mm	100mm to 500mm
374	L374	T374	Elastic Nail	1.5mm to 5.0mm	100mm to 500mm
375	L375	T375	Smart Tibial Nail	8.0mm to 14mm	260mm to 500mm
380	L380	T380	Expert Tibia Interlocking Nail	8.0mm to 14mm	260mm to 500mm
381	L381	T381	Expert Femoral Interlocking Nail	8.0mm to 14mm	260mm to 540mm
377	L377	T377	Antegrade Femoral Nail (AFN)	8.0mm to 14mm	240mm to 440mm
382	L382	T382	Multilock Femoral Nail	8.0mm to 14mm	240mm to 440mm

Date: 2020-12-15
Revision: a




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INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

376	L376	T376	Trochanteric Femoral Nail	9.0mm to 12mm	150mm to 200mm
383	L383	T383	Multilock Humeral Nail	6.0mm to 10mm	100mm to 500mm
378	L378	T378	Unreamed Femoral Nail	8.0mm to 14mm	260mm to 540mm
379	L379	T379	Unreamed Tibia Nail	8.0mm to 14mm	260mm to 540mm
355	L355	T355	End Cap	—	—
392	L392	T392	PFN-2 Nail 125°/135°/130°	9mm to 12mm	170mm to 460mm

Class: IIb
GMDN: 60411

Name: Spine Implants

Trade name(s): HARDIK®

Model(s):

Ref. No. SS 316L	Ref. No. SS 316LVM	Ref. No. TI-6Al-4V	Item Name	Size	Length
401	L401	T401	Monoaxial Screw	3.0mm to 8.0mm	20.0mm to 70.0mm
402	L402	T402	Polyaxial Screw	3.0mm to 8.0mm	20.0mm to 70.0mm
403	L403	T403	Connecting Rod	5.5mm	50mm to 500mm
404	L404	T404		3.0mm	
405	L405	T405	Connecting Block	-	-
406	L406	T406	Reduction Screw	3.5mm to 6.0mm	20.0mm to 70.0mm
407	L407	T407	Threaded Staple	-	-
408	L408	T408	Pedical Hook	-	-
409	L409	T409	Laminar Wide Blade Hook	-	-

Date: 2020-12-15
Revision: a



Mgr. Jiří Heš 
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0466 QS/NB
issued for manufacturer:

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

410	L410	T410	Laminar Reduce Distance Hook	-	-
411	L411	T411	Laminar Angle Blade Hook	-	-
412	L412	T412	Inner Nut	-	-
413	L413	T413	Cervical Plate	-	15.0mm to 100mm
416	L416	T416	Spinal Eco Cage	10mm to 20mm	5.0mm to 100mm
417	L417	T417	Expendable Cage	10mm to 20mm	5.0mm to 100mm
418	L418	T418	Tlif Cage (Kidney Cage)	4° 8° & 11°	4.0mm to 20mm
419	L419	T419	Plif Cage	20mm & 25mm	4.0mm to 20mm
433	L433	T433	Spine H Plate	-	5hole to 20hole

Class: IIb
GMDN: 61325

Name: Arthroscopy Implants

Trade name(s): HARDIK®

Model(s):

Ref. No. SS 316L	Ref. No. SS 316LVM	Ref. No. Ti-6Al-4V	Item Name	Size	Length
315	L315	T315	Cannulated Interference Screws (ACL Screws)	7.0mm to 10.0mm	20.0mm to 50mm
317	-	T317	Endo Buttons	-	-
318	-	T318	Suture Disc	-	-
384	L384	T384	Spiked Washer	4mm to 6.5mm	-
385	L385	T385	Spiked Ligament Staple	6mm to 10mm	-

Class: IIb
Date: 2020-12-15
Revision: a




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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0466 QS/NB
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HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda – 360021, Rajkot, India

GMDN: 62399

Facility(ies):

HARDIK INTERNATIONAL PRIVATE LIMITED
Plot No. G-2041/42/A, Kishan Gate, Lodhika G.I.D.C., Kalawad Road, Metoda –
360021, Rajkot, India

Certificate History:

Revision	Date	Reference Number	Action
-	2019-09-27	803602703	Certification
a	2020-12-15	803602874	Approval of company name change

Date: 2020-12-15
Revision: a



Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Hardik International Private Limited

Plot No. G-2041/42/A,
Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda - 360021,
Rajkot, India

2024-05-24

Confirmation of receipt of a formal application 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

To whom it may concern,

This letter confirms that DQS India (Deutsch Quality Systems (India) Private Limited) has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR. The application has been forwarded to our partner organization, DQS Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO. The application has been submitted for review to the NB prior to 26th of May 2024 for the following manufacturer:

Hardik International Private Limited

Plot No. G-2041/42/A,
Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda - 360021,
Rajkot, India

SRN Number: IN-MF-000007251

The devices covered by the formal application above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received by DQS India and forwarded to DQS Medizinprodukte GmbH and for which DQS Medizinprodukte GmbH is

also responsible for appropriate surveillance of the corresponding devices under the applicable Directive (MDD). In terms of this letter this means that DQS India received either a signed agreement for continuation of MDD surveillance activities from DQS Medizinprodukte GmbH, or a transfer agreement for surveillance of MDD legacy devices from DQS Medizinprodukte GmbH and the outgoing NB. Table 2 identifies the devices for which an MDR application has been received, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

The transition timelines that apply to the devices covered by this letter, from the perspective of DQS India, which are 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)

The intention of this letter is to confirm that no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3. For the transition timelines shown above to apply after 26 September 2024, the notified body and the manufacturer have to sign a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

You can contact DQS India if further information is required, also if it is required by DQS Medizinprodukte GmbH.

On behalf of DQS India



Kalaiselvan K
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 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

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
Bone Screws	Class IIb	N/A	Cert # 190466 QS/NB NB # 1023
Bone Plates	Class IIb	N/A	Cert # 190466 QS/NB NB # 1023
Bone Nails	Class IIb	N/A	Cert # 190466 QS/NB NB # 1023

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-24	50260238CL-01	Initial issue



Certificate No. MD-QMS/91/R/I/2257/f

This is to certify that

Hardik International Private Limited

Plot No. G-2041-42/A, Kishan Gate, Lodhika G.I.D.C.,
Kalawad Road, Metoda - 360 021, Rajkot, India

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope :

Design and Development, Manufacture and Sales of Non-Active, Non-Sterile Medical Devices :

- Bone Screws, Bone Plates, Bone Nails, Bone Pins and Wires, Spinal Implants, Arthroscopy Implants, Endoprosthesis and related Instruments
- External Fixators

Technical Area/s (Ref. IAF MD9) :
A.1.1

Initial Certification : 04/04/2017
Re-certification : 12/04/2023
Valid until : 03/04/2026
(Replaces withdrawn Certificate No.MD-QMS/91/R/I/2257/e issued on 20th October, 2020)



Authorised Signatory

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www.iasonline.org

Issuing Authority: Zenith Quality Assessors Pvt. Ltd.
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Viman Nagar, Pune - 411 014, Maharashtra, India
www.zenith-worldwide.com