

B3-DQ-01-001	Business Development - Engineering	 Technology
	Document Qualité	
Version: V2	Déclaration de conformité produit	

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Nom et adresse de l'entreprise
Name und Adresse der Firma
Nome e indirizzo della ditta
Name and address of the firm

HL Technology SA
Rue Jardinière 153
CH-2300 La Chaux-de-Fonds

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

le dispositif médical
das Medizinprodukt
the medical device
il dispositivo medico

Implant Tool
According to attached list
Product_List_Implant_Tool_v01

de la classe / der Klasse / della classe / of class

I
Nach Anhang IX der Richtlinie 93/43/EWG / selon l'annexe IX de la directive 93/42/CEE /
secondo l'allegato IX della direttiva 93/24/CEE / according to annex IX of direct. 93/42/EEC

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE qui le concernent
allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind
soddisfa tutte le disposizioni della direttiva 93/42/CEE che lo riguardano
meets all the provisions of the directive 93/42/EEC which apply to it.

Normes harmonisées, normes nationales et autres documents normatifs appliqués
Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente
Norme armonizzate o nazionali applicate, altri documenti normativi applicati
Applied harmonised standards, national standards or other normative documents

According to document
Liste des standards applicables Implant Tool_V01

Procédure d'évaluation de la conformité
Konformitätsbewertungsverfahren
Procedimentodi valutazione della conformità
Conformity assessment procedure

Annex VII

Organisme Notifié
Benannte Stelle
Corpo notificato
Notified Body

N/A



LA CHAUX-DE-FONDS, LE 19.05.2021
.....
Lieu, date / Ort, Datum / Luogo, data / Place, date

a.i. FRANCOIS HUGUELET
.....
Adrian Banderet / QMRA Manager

La Chaux-de-Fonds, le 19.05.2021
.....
Lieu, date / Ort, Datum / Luogo, data / Place, date

.....
Julien von Kaenel / CEO

Implant Tool

Information			Class
Article Number HL-TECHNOLOGY	Description HL-TECHNOLOGY	Product Family	I
HLT.IMP-XS-042-1	HDAToolR - Square-Type Driver 0.9mm	Hader Clix	X
HLT.19544P-1	IBD - Straight Driver 24 mm Latch Type	Implant Tool	X
HLT.19545P-1	IBD - SCS Driver 24 mm Latch Type	Implant Tool	X
HLT.19546P-1	IBD - Unigrip Driver 24 mm Latch Type	Implant Tool	X
HLT.19608P-1	IBD - Driver Hex 1.3 mm 24 mm Latch Type	Implant Tool	X
HLT.19542P-1	IBD - Driver Hex 1.2 mm 24 mm Latch Type	Implant Tool	X
HLT.19541P-1	IBD - Driver Hex 0.9 mm 24 mm Latch Type	Implant Tool	X
HLT.14660P-1	IBD - Angled Driver 24 mm Latch Type	Implant Tool	X
HLT.14658P-1	IBD - Driver Hex 1.25 mm 24 mm Latch Type	Implant Tool	X
HLT.14657P-1	IBD - Driver Hex 1.25 mm 17 mm Latch Type	Implant Tool	X
HLT.14659P-1	IBD - Angled Driver 17 mm Latch Type	Implant Tool	X
HLT.14661P-1	IBD - SCS Driver 17 mm Latch Type	Implant Tool	X
HLT.14662P-1	IBD - Unigrip Driver 17 mm Latch Type	Implant Tool	X
HLT.19567P-1	IBD - Driver Hex 1.2 mm 17 mm Latch Type	Implant Tool	X
HLT.17796P-1	IBD - Dynamic Driver 18 mm	Implant Tool	X
HLT.17797P-1	IBD - Dynamic Driver 24 mm	Implant Tool	X
HLT.17798P-1	IBD - Dynamic Driver 32 mm	Implant Tool	X
HLT.19293P-1	IBD - Straight Driver 24 mm Square	Implant Tool	X
HLT.19295P-1	IBD - SCS Driver 24 mm Square	Implant Tool	X
HLT.19297P-1	IBD - Unigrip Driver 24 mm Square	Implant Tool	X
HLT.19289P-1	IBD - Driver Hex 1.3 mm 24 mm Square	Implant Tool	X
HLT.19287P-1	IBD - Driver Hex 1.2 mm 24 mm Square	Implant Tool	X
HLT.17881P-1	IBD - Driver Hex 0.9 mm 24 mm Square	Implant Tool	X
HLT.19291P-1	IBD - Angled Driver 24 mm Square	Implant Tool	X
HLT.19384E-1	IBD - Implant Buddy Dental	Implant Tool	X
HLT.19431P-1	IBD - Short Handle For Driver Bits	Implant Tool	X
HLT.19648P-1	IBD - Multi-Unit Driver Latch Type	Implant Tool	X
HLT.19649P-1	IBD - Multi-Unit Driver Square Type	Implant Tool	X
HLT.19492P-1	IBD - Latch to Square Driver Insert	Implant Tool	X
HLT.19625E-1	IBD - Implant Buddy Latch	Implant Tool	X
HLT.19424P-1	IBD - Driver Hex 0.9 mm 17 mm Square	Implant Tool	X
HLT.19425P-1	IBD - Driver Hex 1.2 mm 17 mm Square	Implant Tool	X
HLT.19430P-1	IBD - Driver Hex 1.25 mm 17 mm Square	Implant Tool	X
HLT.19432P-1	IBD - Driver Hex 1.25 mm 24 mm Square	Implant Tool	X
HLT.19426P-1	IBD - Driver Hex 1.3 mm 17 mm Square	Implant Tool	X
HLT.19427P-1	IBD - Angled Driver 17 mm Square	Implant Tool	X
HLT.19428P-1	IBD - SCS Driver 17 mm Square	Implant Tool	X
HLT.19429P-1	IBD - Unigrip Driver 17 mm Square	Implant Tool	X