

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

Hader Dental Attachments
According to attached list
Product_List_HaderDentalAttachments_V01

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

IIA
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
ApplicableStandards_HaderDentalAttachment_V01

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

Annex II

Organisme Notifié
Banannte Stelle
Corpo notificato
Notified Body

SQS (CE 1250)
Swiss Association for Quality and Management Systems
Bernstrasse 103
3052 Zollikofen
Switzerland

La Chaux-de-Fonds, le 12 Mai 2021
Lieu, date / Ort, Datum / Luogo, data / Place, date


Adrian Banderet / QMRA Director

La Chaux-de-Fonds, le 12 Mai 2021
Lieu, date / Ort, Datum / Luogo, data / Place, date


Julien von Kaenel / CEO

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Hader Dental Attachment

Information			Class
Article Number HL-TECHNOLOGY	Description HL-TECHNOLOGY	Product Family	IIA
HLT.1201A-1	Hader Ball Female Housing Or	Hader Clix	X
HLT.1203A-1	Hader Ball Female Housing Pall	Hader Clix	X
HLT.1205A-1	Hader Ball Female Housing Ti	Hader Clix	X
HLT.1205A-215-1	Hader Ball Female Housing Titan	Hader Clix	X
HLT.1206C-1	Hader Clix Threaded Male	Hader Clix	X
HLT.1206CL-1	Hader Clix Threaded Male Long	Hader Clix	X
HLT.1231-1	Hader Clix Female Clips Yellow	Hader Clix	X
HLT.1232-1	Hader Clix Female Clips White	Hader Clix	X
HLT.1233-1	Hader Clix Female Clips Red	Hader Clix	X
HLT.1271C-1	Hader Clix Mâle à Sceller	Hader Clix	X
HLT.1291C-1	Hader Clix Pivot Cylindrique	Hader Clix	X
HLT.1293C-1	Hader Clix Pivot fileté	Hader Clix	X
HLT.EMB1201C-1	Hader Ball Mâle Ancrofluct	Hader Clix	X
HLT.EMB1203C-1	Hader Ball Mâle Pall	Hader Clix	X
HLT.EMB1209C-1	Hader Ball Mâle Novostil	Hader Clix	X
HLT.EMB1235-1	Hader Clix Metal Housing	Hader Clix	X
HLT.EMBRA0063-1	Anneau De Rétention De Base	Hader Clix	X
HLT.EMBRA0064-1	Anneau De Rétention De Base Noprax CrCo	Hader Clix	X
HLT.RE4600TI-1	Anneau de Base à Sceller	Hader Clix	X
HLT.1706-1	Hader Rider Housing 2	Hader Rider	X
HLT.1802-1	Hader Rider Cavalier Yellow	Hader Rider	X
HLT.1805-1	Hader Rider Cavalier White	Hader Rider	X
HLT.1806-1	Hader Rider Cavalier Red	Hader Rider	X
HLT.19346P-1	Hader Rider Metal Housing 2	Hader Rider	X
HLT.1311-1	Hader Sagix Matrize 1.7 Yellow	Hader Sagix	X
HLT.1312-1	Hader Sagix Matrize 1.7 White	Hader Sagix	X
HLT.1313-1	Hader Sagix Matrize 1.7 Red	Hader Sagix	X
HLT.1322-1	Hader Sagix Patrize 1.7 Noprax CrCo	Hader Sagix	X
HLT.1325-1	Hader Sagix Metal Housing 1.7	Hader Sagix	X

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HLT.1361-1	Hader Sagix Matrize 2.2 Yellow	Hader Sagix	X
HLT.1362-1	Hader Sagix Matrize 2.2 White	Hader Sagix	X
HLT.1363-1	Hader Sagix Matrize 2.2 Red	Hader Sagix	X
HLT.1372-1	Hader Sagix Patrize 2.2 CrCo	Hader Sagix	X
HLT.1373-1	Hader Sagix Patrize M2 fileté	Hader Sagix	X
HLT.1374-1	Hader Sagix Patrize PSAG CAD/CAM	Hader Sagix	X
HLT.1375-1	Hader Sagix Metal Housing 2.2	Hader Sagix	X
HLT.19284P-1	Hader Sagix Universal Threaded Ball 2.2	Hader Sagix	X
HLT.EMBRA0063-1	Anneau De Rétention De Base	Hader Sagix	X
HLT.EMBRA0064-1	Anneau De Rétention De Base Noprax CrCo	Hader Sagix	X