Statement of reasons for why the placing surgical tool reusable on the market under 93/42/CEE after the 26 of May 2021 is allowed

Modifications Matrix					
Rev.	Description of the modifications	DCM	Fonction	Nom	Date
1	Initiale version	1274	QMRA	A.Banderet	04.04.2023

Function	Name	Date	Signature
Approval :			
Project Manager	V. Perrenoud	04.04.23	
Engineering	M. Risold	04.04.2023	
QMRA	A. Banderet	04.04.2023	
Validation date: **Last signature**			

Table of contents

1 Purpose

The aim of this document is to justify the using

- Hader Dental Attachment Tools Reusable (HDAToolsR)
- Implant Tool
- Omega torque wrench (OMEGA)
- Lucky torque wrench (LUCKY)

under the directive 93/42/CEE after the 26th of May 2021.

Declaration of conformity and link to instruction for use available in appendix.

2 Rationale

2.1 Standards applied

European directive 93/42/EEC

Medical device Regulation EU 2017/745

MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

2.2 Applicable data

Article 120 of the medical device regulation

By way of derogation from Article 5 of this Regulation, a **device which is a class I** device pursuant to Directive 93/42/EEC, for which the **declaration of conformity was drawn up prior to 26 May 2021** and for which the **conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body(1)**, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose(2). However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance(3), registration of economic operators(4) and of devices shall apply in place of the corresponding requirements in those Directives.

Article 52 – Paragraph 7 of the medical device regulation

Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited:

Extract of HDAToolsR instruction for use

1 System Description

Hader Dental Attachments Tools are the devices completing the Hader Dental Attachments, which are 3 families' clip-on attachment systems. The devices are used to hold a partial or complete removable denture in the mouth of the patient.

Additional tools are required to prepare and mount these elements in the patient's mouth. These class I tools are explained in this technical file.

The Hader Dental Attachment Tools (HDATools) are reusable elements and have to respect cleaning and re-sterilization methods. It is used in the chairside for the preparation of the canal root. However, there is one exception for the screwdriver, which is used in the dentist's office and the laboratory.

Extract of Implant tool instruction for use

1.5 Warnings/ Precautions

It is important to check the following points before use.

- Make sure the retreatment (disinfection and sterilization) has been carried out before each use.
- To have chosen the good driver according to the screws.
- To respect the recommendations of the Implant manufacturer concerning the tightening torque.

Extract of OMEGA instruction for use

Description of the torque Wrench

Torque wrench kit consisting of:
1x Torque wrench
1x Tube of grease

Option: adjustment wrench

The torque wrench, with torque adjustment, is a dental device which allows the tightening and loosening of screws, prosthetic elements, and implants; it is a precision, easy to disassemble instrument, delivered unsterilized. In order to guarantee its proper operation, the torque wrench must be 1) disassembled, 2) cleaned, 3) disinfected 4) assembled/greased, and 5) sterilised before the first use and after each use by following the instructions described below;

Extract of LUCKY instruction for use

Description of the torque wrench

Torque wrench kit consisting of:
1x Torque wrench
1x Tube of grease

The torque wrench, with fixed torque, is a dental device which allows the tightening and loosening of screws, prosthetic elements, and implants; it is a precision, easy to disassemble instrument, delivered unsterilized. In order to guarantee its proper operation, the torque wrench must be 1) disassembled, 2) cleaned, 3) disinfected 4) assembled/greased, and 5) sterilized before the first use and after each use by following the instructions described below;

The handling and use of the product are carried out without direct control on our part and remain the responsibility of the user. No responsibility may be attributed to us for damages resulting from improper use.

3 Justification / conclusion

3.1 Summary

Based on the information's provide in chapter two, we could summarize the situation with the fours main points of article 120 of the medical device regulations

- requires the involvement of a notified body(1)

All device describe below are classified as class I reusable (surgical tool reusable) under the medical device regulation and will need involvement by a notified body

- there are no significant changes in the design and intended purpose(2).

No significant changes after the Declarations of conformities signature

- However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance(3)

Quality management system, as well as post market activities have been done according to medical device regulation requierement

- registration of economic operators(4)

Mandate for representation in EU is signed with our EU Representative as well as quality agreement with distributors following the requirements of the medical device regulation

3.2 Conclusion

Based on the information's provided in this report, we can conclude that:

- Hader Dental Attachment Tools Reusable (HDAToolsR)
- Implant Tool (IFU document named "Implant Buddy")
- Omega torque wrench (OMEGA)
- Lucky torque wrench (LUCKY)

Could continue to be placed on the market under medical device directive (93/42/EEC) following article 120 of the Medical Device Regulation

4 Appendix

- EC-Declaration of Conformity_HDATool_V01 (Declaration of conformity included single use devices that are not concerned by this report)
- EC-Declaration of Conformity Implant Tool_V02
- B3-DQ-01-001 V02 Déclaration de conformité OMEGA
- Déclaration de conformité LUCKY
- https://www.hl-technology.ch/en/IFU/

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 Tool (HDAtool) According to attached list Product_List_HDATool_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 direttiva93/24/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.

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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 HDATool_V01
Procédure d'évaluation de la conformité Konformitätsbewertungsverfahren Procedimentodi valutazione della conformità Conformity assessment procedure	Annex VII
Organisme Notifé Banannte Stelle Corpo notificato Notified Body	N/A

La Chaux-de-Fonds le 06.05.2021
Lieu, date / Ort, Datum / Luogo, data / Place, date

Adrian Banderet / QMRA Manager

La Chaux-de-Fonds, le 06.05.2021
Lieu, date / Ort, Datum / Luogo, data / Place, date

Julien von Kaenel / CEO

Hader Dental Attachments Tool

Information			Class
Article Number HL-TECHNOLOGY	Description HL-TECHNOLOGY	Product Family	I
HLT.1227-1	HDATooIR - Hader Clix Penetration Drill	Hader Clix	X
HLT.1228-1	HDATooIR - Hader Clix Root Face Radix	Hader Clix	X
HLT.1229-1	HDATooIR - Hader Clix Spiral Bur Radix	Hader Clix	X
HLT.1251B-1	HDAToolSU - O-Ring Spacer	Hader Clix	X
HLT.EMBREH17-1	HDAToolSU - Hader Clix Protection Cap	Hader Clix	X
HLT.IMP-XS-042-1	HDATooIR - Square-Type Driver 0.9mm	Hader Clix	X
HLT.REH2-1	HDAToolSU - Impression Auxiliary	Hader Clix	X

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Nom et adresse de l'entreprise Name und Adresse der Firma Nome e indirizzo della ditta Name and address of the firm	*HL Technology* *Rue Jardinière 153* *2300 La Chaux-de-Fonds* *CH*

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	*Clé Dynamométrique OMEGA* Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl Nom, type ou modèle, numéro de lot ou série, év. source et nombre d'exemplaires Nome, tipo o modello, numero di lotto o di serie, ev. fonte e numero di esemplari Name, type or model, batch or serial number, possibly sources and number of items
de la classe / der Klasse / della classe / of class	*Classe I* Nach Anhang IX der Richtlinie 93/43/EWG / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva93/24/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 (od. 90/385/EWG) entspricht, die anwendbar sind / soddisfa tutte le disposizioni della direttiva 93/42/CEE (opure 90/385/CEE) che lo riguardano / meets all the provisions of the directive 93/42/EEC (or 90/385/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	*Normes harmonisées, ISO 7153-1 ; ISO 13485 ; NF EN 1041 ; EN ISO 15233-1*
Procédure d'évaluation de la conformité Konformitätsbewertungsverfahren Procedimentodi valutazione della conformità Conformity assessment procedure	B3-PR-01 V04 Conception des produits
Organe resp. de l'évaluat. de la conformité (si consulté) Konformitätsbewertungsstelle (falls beigezogen) Organo incaric. della valutaz. della conform. (se consultato) Notified Body (if consulted)	N/A

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17.02.2020, La Chaux-de-Fonds
Lieu, date / Ort, Datum / Luogo, data / Place, date

Adrian Bardaret, QMRA Manager
Nom et fonction /Name und Funktion / Nome e funzione / Name and function

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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* *Rue Jardinière 153* *2300 La Chaux-de-Fonds* *CH*

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le dispositif médical das Medizinprodukt the medical device il dispositivo medico	*Clé Dynamométrique LUCKY* Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl Nom, type ou modèle, numéro de lot ou série, év. source et nombre d'exemplaires Nome, tipo o modello, numero di lotto o di serie, ev. fonte e numero di esemplari Name, type or model, batch or serial number, possibly sources and number of items
de la classe / der Klasse / della classe / of class	*Classe I* Nach Anhang IX der Richtlinie 93/43/EWG / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva93/24/CEE / according to annex IX of direct. 93/42/EEC

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Organe resp. de l'évaluat. de la conformité (si consulté) Konformitätsbewertungsstelle (falls beigezogen) Organo incaric. della valutaz. della conform. (se consultato) Notified Body (if consulted)	N/A

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La Chaux-de-Fonds, le 08.04.2020
Lieu, date / Ort, Datum / Luogo, data / Place, date

Adrian Barderet - QMRA Manager
Nom et fonction /Name und Funktion / Nome e funzione / Name and function

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 direttiva93/24/CEE / according to annex IX of direct. 93/42/EEC

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Procédure d'évaluation de la conformité Konformitätsbewertungsverfahren Procedimentodi valutazione della conformità Conformity assessment procedure	Annex VII
Organisme Notifé Banannte Stelle Corpo notificato Notified Body	N/A

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LA CHAUX-DE-FONDS, CE 19.05.2021 — a.i. FRANCOIS HUGUELET
Lieu, date / Ort, Datum / Luogo, data / Place, date — Adrian Banderet / QMRA Manager

La Chaux-de-Fonds, le 19.05.2021 — J
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