

B3 - R&D	
Simple Template	
B3-FO-61-19 v1 Rationale	

ADDENDUM to EC- DeclarationofConformity_HaderDentalAttachements_V01_Rev2

Function	Name	Date	Signature
Approval :			
PRRC	A. Banderet		
QMRA	S. Hofer		
Validation date: Last signature			

Modifications Matrix				
Rev.	Description of the modifications	Function	Name	Date
1	Addendum to reflect all the item commercial references used by Hader Solutions & distribution Ltd. and Alphadent NV that include medical devices from Hader Dental Attachments family.	QMRA	A.Banderet	17.04.23
2	1. Change of Manufacturer: Hader Solutions & Distribution Ltd, effective April 24, 2024. 2. Change of Notified Body: Surveillance responsibility transferred to National Standards Authority of Ireland (NSAI, Body No. 0050), effective July 19, 2024. 3. Addition of Economic Operator: Theia Holding SA, Rue Jardinière 153, CH-2300 La Chaux-de-Fonds, Switzerland, as the Swiss Authorized Representative, effective November 25, 2025. 4. Validity Extension: Compliance under Regulation (EU) 2023/607 extended until December 31, 2028.	PRRC	A.Banderet	25.11.24

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1 Purpose

This addendum to the document “EC-DeclarationofConformity_HaderDentalAttachments_V01” reflects the following updates:

1. Change of Manufacturer: Hader Solutions & Distribution Ltd, effective April 24, 2024.
2. Change of Notified Body: Surveillance responsibility transferred to National Standards Authority of Ireland (NSAI, Body No. 0050), effective July 19, 2024.
3. Addition of Economic Operator: Theia Holding SA, Rue Jardinière 153, CH-2300 La Chaux-de-Fonds, Switzerland, as the Swiss Authorized Representative, effective November 25, 2025.
4. Validity Extension: Compliance under Regulation (EU) 2023/607 extended until December 31, 2028.

This addendum ensures compliance while retaining the original Declaration of Conformity as the primary document.

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2 List of product

CE Class	Product family	Commercial reference	Description
HLT CLASS IIA	HADER CX	5011002	Hader CX Combo Females 6 PCS
HLT CLASS IIA	HADER CX	1234	PRECI-CLIX COMBI 2+2+2
HLT CLASS IIA	HADER CX	5011003-1	Hader Round Female Housing Orax
HLT CLASS IIA	HADER CX	1201 A	PRECI-BALL FEMALE STD OR 1 P.
HLT CLASS IIA	HADER CX	5011003-20	Hader Round Female Housing Orax - 20 PCS
HLT CLASS IIA	HADER CX	1201 AB	1201 AB
HLT CLASS IIA	HADER CX	5011005-1	Hader Round Female Housing Ti
HLT CLASS IIA	HADER CX	1205 A	PRECI-BALL FEMALE TI 1 P.
HLT CLASS IIA	HADER CX	5011005-20	Hader Round Female Housing Ti - 20 PCS
HLT CLASS IIA	HADER CX	1205 AB	PRECI-BALL FEMALE TI 20 PCS
HLT CLASS IIA	HADER CX	5011010-1	Hader CX Threaded Male Ball
HLT CLASS IIA	HADER CX	1206 C	PRECI-BALL/CLIX MALE V 1 P.
HLT CLASS IIA	HADER CX	5011011-1	Hader CX Threaded Male Ball Long
HLT CLASS IIA	HADER CX	1206 CL	PRECI-BALL/CLIX PATRIX V LONG 1 P.
HLT CLASS IIA	HADER CX	5011019-30	Hader CX Female Clips Yellow 30 PCS
HLT CLASS IIA	HADER CX	1231B	PRECI-CLIX FEM. YELLOW 30 PCS
HLT CLASS IIA	HADER CX	5011019-6	Hader CX Female Clips Yellow 6 PCS
HLT CLASS IIA	HADER CX	1231	PRECI-CLIX FEMALE YELLOW 6 PCS
HLT CLASS IIA	HADER CX	5011020-30	Hader CX Female Clips White 30 PCS
HLT CLASS IIA	HADER CX	1232B	PRECI-CLIX FEMALE WHITE 30 PCS
HLT CLASS IIA	HADER CX	5011020-6	Hader CX Female Clips White 6 PCS
HLT CLASS IIA	HADER CX	1232	PRECI-CLIX FEMALE WHITE 6 PCS
HLT CLASS IIA	HADER CX	5011021-30	Hader CX Female Clips Red 30 PCS
HLT CLASS IIA	HADER CX	1233B	PRECI-CLIX FEMALE RED 30 PCS
HLT CLASS IIA	HADER CX	5011021-6	Hader CX Female Clips Red 6 PCS
HLT CLASS IIA	HADER CX	1233	PRECI-CLIX FEMALE RED 6 PCS
HLT CLASS IIA	HADER CX	5011022-30	Hader CX Metal Housing 30 PCS
HLT CLASS IIA	HADER CX	1235B	PRECI-CLIX HOUSING 30 PCS
HLT CLASS IIA	HADER CX	5011022-6	Hader CX Metal Housing 6 PCS
HLT CLASS IIA	HADER CX	1235	PRECI-CLIX HOUSING 6 PCS
HLT CLASS IIA	HADER CX	5011025-1	Hader CX Titanax Male
HLT CLASS IIA	HADER CX	1271 C	PRECI-CLIX MALE TI 1 P.
HLT CLASS IIA	HADER CX	5011028-1	Hader CX Threaded Post Only
HLT CLASS IIA	HADER CX	1291 C	PRECI-CLIX CANAL POST 1 P.
HLT CLASS IIA	HADER CX	5011029-1	Hader CX Pivot One piece Ball & Post



CE Class	Product family	Commercial reference	Description
HLT CLASS IIA	HADER CX	1293 C	PRECI-CLIX C POST 1 P.
HLT CLASS IIA	HADER CX	5011037-1	Hader Threaded Base Ring
HLT CLASS IIA	HADER CX	RA 0063	REVAX M2 BASE RING IR 1 P.
HLT CLASS IIA	HADER CX	5011038-1	Hader Threaded Base Ring CrCo
HLT CLASS IIA	HADER CX	RA 0064	PRECI-SAGIX BASE RING NOPRAX 1 P.
HLT CLASS IIA	HADER CX	5011042-1	Hader Cemented Male Base
HLT CLASS IIA	HADER CX	RE 4600 TI	PRECI-CLIX THREADS TI 1 P.
HLT CLASS IIA	HADER CX	5012001	Hader CX Female Set
HLT CLASS IIA	HADER CX	1242	PRECI-CLIX FEMALE SET
HLT CLASS IIA	HADER CX	5012002	Hader CX 002
HLT CLASS IIA	HADER CX	1251	PRECI-CLIX ATI
HLT CLASS IIA	HADER CX	5012003	Hader CX 003
HLT CLASS IIA	HADER CX	1252	PRECI-CLIX AP
HLT CLASS IIA	HADER CX	5012005	Hader CX 005
HLT CLASS IIA	HADER CX	1261	PRECI-CLIX CV
HLT CLASS IIA	HADER CX	5012006	Hader CX 006
HLT CLASS IIA	HADER CX	1271	PRECI-CLIX TI-TI
HLT CLASS IIA	HADER CX	5012007	Hader CX 007
HLT CLASS IIA	HADER CX	1272	PRECI-CLIX P-TI
HLT CLASS IIA	HADER CX	5012008	Hader CX 008
HLT CLASS IIA	HADER CX	1276	PRECI-CLIX TI-V
HLT CLASS IIA	HADER CX	5012009	Hader CX 009
HLT CLASS IIA	HADER CX	1277	PRECI-CLIX P-V
HLT CLASS IIA	HADER CX	5012010	Hader CX 010
HLT CLASS IIA	HADER CX	1281	PRECI-CLIX TI-P
HLT CLASS IIA	HADER CX	5012011	Hader CX 011
HLT CLASS IIA	HADER CX	1282	PRECI-CLIX P-P
HLT CLASS IIA	HADER CX	5012012	Hader CX 012
HLT CLASS IIA	HADER CX	1291	PRECI-CLIX RTI
HLT CLASS IIA	HADER CX	5012013	Hader CX 013
HLT CLASS IIA	HADER CX	1292	PRECI-CLIX RP
HLT CLASS IIA	HADER CX	5012014	Hader CX 014
HLT CLASS IIA	HADER CX	1293	PRECI-CLIX RCT
HLT CLASS IIA	HADER CX	5012015	Hader CX 015
HLT CLASS IIA	HADER CX	1294	PRECI-CLIX RCP
HLT CLASS IIA	HADER CX	5012016	Hader CX 016 CAD CAM
HLT CLASS IIA	HADER CX	1261 CC	PRECI-CLIX CV CAD-CAM
HLT CLASS IIA	HADER CX	5012017	Hader CX 017 CAD CAM
HLT CLASS IIA	HADER CX	1271 CC	PRECI-CLIX TI-TI CAD-CAM



CE Class	Product family	Commercial reference	Description
HLT CLASS IIA	HADER CX	5012018	Hader CX 018 CAD CAM
HLT CLASS IIA	HADER CX	1272 CC	PRECI-CLIX P-TI CAD-CAM
HLT CLASS IIA	HADER CX	5012019	Hader CX 019 CAD CAM
HLT CLASS IIA	HADER CX	1276 CC	PRECI-CLIX TI-V CAD-CAM
HLT CLASS IIA	HADER CX	5012020	Hader CX 020 CAD CAM
HLT CLASS IIA	HADER CX	1277 CC	PRECI-CLIX P-V CAD-CAM
HLT CLASS IIA	HADER CX	5013001	Hader CX Dentists Starter Kit 001
HLT CLASS IIA	HADER CX	1297	PRECI-CLIX RC SET DENTIST
HLT CLASS IIA	HADER CX	5013002	Hader CX Dentists Starter Kit 002
HLT CLASS IIA	HADER CX	1299	PRECI-CLIX SET DENTIST
HLT CLASS IIA	HADER CX	5013002	Hader CX Dentists Starter Kit 002
HLT CLASS IIA	HADER CX	1299	PRECI-CLIX SET DENTIST
HLT CLASS IIA	HADER CX	5013003	Hader CX Lab Starter Kit 003
HLT CLASS IIA	HADER CX	TBD	Hader CX Lab Starter Kit 003
HLT CLASS IIA	HADER VX	5021004-30	Hader VX Traditional Metal Housing 30 PCS
HLT CLASS IIA	HADER VX	1706B	PRECI-HORIX HOUSING 30 PCS
HLT CLASS IIA	HADER VX	5021004-6	Hader VX Traditional Metal Housing 6 PCS
HLT CLASS IIA	HADER VX	1706	PRECI-HORIX HOUSING 6 PCS
HLT CLASS IIA	HADER VX	5021005-30	Hader VX Alignment Metal Housing 30 PCS
HLT CLASS IIA	HADER VX	1710B	PRECI-HORIX ALIGNMENT METAL HOUSING 30pcs
HLT CLASS IIA	HADER VX	5021005-6	Hader VX Alignment Metal Housing 6 PCS
HLT CLASS IIA	HADER VX	1710	PRECI-HORIX ALIGNMENT METAL HOUSING 6 pcs
HLT CLASS IIA	HADER VX	5021010-30	Hader VX Yellow Female-Standard 30 PCS
HLT CLASS IIA	HADER VX	1802B	PRECI-VERTIX/HORIX FEMALE YELLOW 30 PCS
HLT CLASS IIA	HADER VX	5021010-6	Hader VX Yellow Female-Standard 6 PCS
HLT CLASS IIA	HADER VX	1802	PRECI-VERTIX/HORIX FEMALE YELLOW 6 PCS
HLT CLASS IIA	HADER VX	5021011-30	Hader VX White Female-Decreased 30 PCS
HLT CLASS IIA	HADER VX	1805B	PRECI-VERTIX/HORIX FEMALE WHITE 30 PCS
HLT CLASS IIA	HADER VX	5021011-6	Hader VX White Female-Decreased 6 PCS
HLT CLASS IIA	HADER VX	1805	PRECI-VERTIX/HORIX FEMALE WHITE 6 PCS
HLT CLASS IIA	HADER VX	5021012-30	Hader VX Red Female-Increased 30 PCS
HLT CLASS IIA	HADER VX	1806B	PRECI-VERTIX/HORIX FEMALE RED 30 PCS
HLT CLASS IIA	HADER VX	5021012-6	Hader VX Red Female-Increased 6 PCS
HLT CLASS IIA	HADER VX	1806	PRECI-VERTIX/HORIX FEMALE RED 6 PCS
HLT CLASS IIA	HADER VX	5021020	Set of 6 Hader VX female inserts: 2 yellow, 2 white, 2 red
HLT CLASS IIA	HADER VX	1807	PRECI-VERTIX/HORIX MIX 2+2+2
HLT CLASS IIA	HADER VX	5021022	Set of 50 Hader VX female inserts: 25 yellow, 10 white, 15 red
HLT CLASS IIA	HADER VX	1807B	PRECI-VERTIX/HORIX MIX 25+10+15



CE Class	Product family	Commercial reference	Description
HLT CLASS IIA	HADER VX	5022001	Hader VX S Kit
HLT CLASS IIA	HADER VX	1701	PRECI-HORIX STANDARD
HLT CLASS IIA	HADER VX	5022002	Hader VX C Kit
HLT CLASS IIA	HADER VX	1741	PRECI-HORIX COMBI
HLT CLASS IIA	HADER VX	5022003	Hader VX Plastic Wax Set
HLT CLASS IIA	HADER VX	1731	PRECI-HORIX PW SET
HLT CLASS IIA	HADER VX	5022004	Hader VX Service Set
HLT CLASS IIA	HADER VX	1737	PRECI-HORIX SERVICE SET
HLT CLASS IIA	HADER VX	5022005	Hader VX Extracoronal Slide Set A
HLT CLASS IIA	HADER VX	1801	PRECI-VERTIX STD SET
HLT CLASS IIA	HADER VX	5022006	Hader VX A Kit Cad Cam
HLT CLASS IIA	HADER VX	1741 CC	PRECI-HORIX COMBI CAD-CAM
HLT CLASS IIA	HADER VX	5022007	Hader VX A Kit Cad Cam
HLT CLASS IIA	HADER VX	1811 CC	PRECI-VERTIX P SET CAD-CAM
HLT CLASS IIA	HADER VX	5022008	Hader VX Extracoronal Slide Set B
HLT CLASS IIA	HADER VX	1811	PRECI-VERTIX P SET
HLT CLASS IIA	HADER VX	5022009	Hader VX Extracoronal Slide Set C
HLT CLASS IIA	HADER VX	1812	PRECI-VERTIX P COMBI SET
HLT CLASS IIA	HADER SX	5031001	Hader SX 1.7 Combi Females 6 PCS
HLT CLASS IIA	HADER SX	1314	PRECI-SAGIX 1,7 FEMALE 2+2+2
HLT CLASS IIA	HADER SX	5031002	Hader SX 2.2 Combi Females 6 PCS
HLT CLASS IIA	HADER SX	1364	PRECI-SAGIX 2,2 FEMALE 2+2+2
HLT CLASS IIA	HADER SX	5031004-30	Hader SX 1.7 Yellow Female 30 PCS
HLT CLASS IIA	HADER SX	1311B	PRECI-SAGIX 1.7 FEMALE YELLOW 30 PCS
HLT CLASS IIA	HADER SX	5031004-6	Hader SX 1.7 Yellow Female 6 PCS
HLT CLASS IIA	HADER SX	1311	PRECI-SAGIX 1.7 FEMALE YELLOW 6 PCS
HLT CLASS IIA	HADER SX	5031005-30	Hader SX 1.7 White Female 30 PCS
HLT CLASS IIA	HADER SX	1312B	PRECI-SAGIX 1.7 FEMALE WHITE 30 PCS
HLT CLASS IIA	HADER SX	5031005-6	Hader SX 1.7 White Female 6 PCS
HLT CLASS IIA	HADER SX	1312	PRECI-SAGIX 1.7 FEMALE WHITE 6 PCS
HLT CLASS IIA	HADER SX	5031006-30	Hader SX 1.7 Red Female 30 PCS
HLT CLASS IIA	HADER SX	1313B	PRECI-SAGIX 1.7 FEMALE RED 30 PCS
HLT CLASS IIA	HADER SX	5031006-6	Hader SX 1.7 Red Female 6 PCS
HLT CLASS IIA	HADER SX	1313	PRECI-SAGIX 1.7 FEMALE RED 6 PCS
HLT CLASS IIA	HADER SX	5031009-2	Hader SX Cast Male 1.7 Noprax CrCo 2 PCS
HLT CLASS IIA	HADER SX	1322	PRECI-SAGIX 1.7 MALE M NP 2 PCS
HLT CLASS IIA	HADER SX	5031009-20	Hader SX Cast Male 1.7 Noprax CrCo 20 PCS
HLT CLASS IIA	HADER SX	1322B	PRECI-SAGIX 1.7 MALE M NP 20 PCS
HLT CLASS IIA	HADER SX	5031011-2	Hader SX Metal Housing 1.7 2 PCS



CE Class	Product family	Commercial reference	Description
HLT CLASS IIA	HADER SX	1325	PRECI-SAGIX 1.7 HOUSING 2 PCS
HLT CLASS IIA	HADER SX	5031011-20	Hader SX Metal Housing 1.7 20 PCS
HLT CLASS IIA	HADER SX	1325B	PRECI-SAGIX 1.7 HOUSING 20 PCS
HLT CLASS IIA	HADER SX	5031013-30	Hader SX 2.2 Yellow Female 30 PCS
HLT CLASS IIA	HADER SX	1361B	PRECI-SAGIX 2.2 FEMALE YELLOW 30 PCS
HLT CLASS IIA	HADER SX	5031013-6	Hader SX 2.2 Yellow Female 6 PCS
HLT CLASS IIA	HADER SX	1361	PRECI-SAGIX 2.2 FEMALE YELLOW 6 PCS
HLT CLASS IIA	HADER SX	5031014-30	Hader SX 2.2 White Female 30 PCS
HLT CLASS IIA	HADER SX	1362B	PRECI-SAGIX 2.2 FEMALE WHITE 30 PCS
HLT CLASS IIA	HADER SX	5031014-6	Hader SX 2.2 White Female 6 PCS
HLT CLASS IIA	HADER SX	1362	PRECI-SAGIX 2.2 FEMALE WHITE 6 PCS
HLT CLASS IIA	HADER SX	5031015-30	Hader SX 2.2 Red Female 30 PCS
HLT CLASS IIA	HADER SX	1363B	PRECI-SAGIX 2.2 FEMALE RED 30 PCS
HLT CLASS IIA	HADER SX	5031015-6	Hader SX 2.2 Red Female 6 PCS
HLT CLASS IIA	HADER SX	1363	PRECI-SAGIX 2.2 FEMALE RED 6 PCS
HLT CLASS IIA	HADER SX	5031018-2	Hader SX Cast Male 2.2 CrCo 2 PCS
HLT CLASS IIA	HADER SX	1372	PRECI-SAGIX 2.2 MALE M NP 2 PCS
HLT CLASS IIA	HADER SX	5031018-20	Hader SX Cast Male 2.2 CrCo 20 PCS
HLT CLASS IIA	HADER SX	1372B	PRECI-SAGIX 2.2 MALE M NP 20 PCS
HLT CLASS IIA	HADER SX	5031019-1	Hader SX 2.2 Noprax Threaded Male
HLT CLASS IIA	HADER SX	1373	PRECI-SAGIX 2.2 MALE V NP 1 P.
HLT CLASS IIA	HADER SX	5031021-2	Hader SX Metal Housing 2.2 2 PCS
HLT CLASS IIA	HADER SX	1375	PRECI-SAGIX 2.2 HOUSING 2 PCS
HLT CLASS IIA	HADER SX	5031021-20	Hader SX Metal Housing 2.2 20 PCS
HLT CLASS IIA	HADER SX	1375B	PRECI-SAGIX 2.2 HOUSING 20 PCS
HLT CLASS IIA	HADER SX	5031023-1	Hader SX Universal Threaded Ball 2.2
HLT CLASS IIA	HADER SX	1374	PRECI-SAGIX 2.2 MALE VTI 1 P.
HLT CLASS IIA	HADER SX	5032001	Hader SX 1.7 Complete Plastic w/Housing
HLT CLASS IIA	HADER SX	5032002	Hader SX 1.7 Complete Plastic
HLT CLASS IIA	HADER SX	5032003	Hader SX 2.2 Complete Plastic w/Housing
HLT CLASS IIA	HADER SX	5032004	Hader SX 2.2 Complete Plastic
HLT CLASS IIA	HADER SX	5032005	Hader SX 1.7 Complete Metal w/Housing
HLT CLASS IIA	HADER SX	5032006	Hader SX 1.7 Complete Metal
HLT CLASS IIA	HADER SX	5032007	Hader SX 2.2 Complete Metal w/Housing
HLT CLASS IIA	HADER SX	5032008	Hader SX 2.2 Complete Metal
HLT CLASS IIA	HADER SX	5032009	Hader SX Complete Threaded Male
HLT CLASS IIA	HADER SX	5032010	Hader SX Complete Threaded Male with Housing
HLT CLASS IIA	HADER SX	5033001	Hader SX Starter Kit Plastic Male
HLT CLASS IIA	HADER SX	1301	PRECI-SAGIX INTRO KIT P

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CE Class	Product family	Commercial reference	Description
HLT CLASS IIA	HADER SX	5033002	Hader SX Starter Kit Cast-to Metal Male
HLT CLASS IIA	HADER SX	1303	PRECI-SAGIX INTRO KIT M

3 Updates to the Declaration

Manufacturer Details:

- Previous Manufacturer: HL Technology SA, Rue Jardinière 153, CH-2300 La Chaux-de-Fonds, Switzerland
- New Manufacturer: Hader Solutions & Distribution Ltd, [Insert Address, Dublin, Ireland], effective April 24, 2024.

Notified Body Details:

- Previous Notified Body: SQS [CE1250], Bernstrasse 103, 3052 Zollikofen, Switzerland
- New Notified Body: National Standards Authority of Ireland (NSAI) [CE0050], 1 Swift Square, Northwood, Santry, Dublin 9, Ireland

Economic Operator:

- Designated Swiss Authorized Representative: Theia Holding SA, Rue Jardinière 153, CH-2300 La Chaux-de-Fonds, Switzerland, effective November 25, 2025.

Validity Extension:

- Declaration validity extended to December 31, 2028, under Regulation (EU) 2023/607.

4 Appendix

The following documents are appended to this addendum:

- EC-DeclarationofConformity_HaderDentalAttachments_V01.
- Confirmation of Transfer Agreement, dated July 5, 2024.
- Confirmation Change Notification_Manufacturer, dated April 24, 2024.
- 230609-final_mdr_manufacturer-declaration_Signed.