

EU Declaration of Conformity

Manufacturer	DIRECTA AB Finvids väg 8 SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999511AP
Product and trade name	TrollByte Kimera, TrollByte Lynx, TrollByte Ezsoft
Product code/REF	As per listed in TF35_List of item number Rev.12
Intended purpose	Holders to accurately hold dental x-ray sensors, image plates and films during x-ray of teeth. Intended user is professional licensed dentist.
Risk Class	Class I, rule 5
Common specification (CS)	N/A
Notified body	N/A
Conformity Assessment Procedure	Article 52, paragraph 7
Statement	This EU declaration of conformity is issued by under the sole responsibility of Directa AB. The device covered by this declaration is in conformity with Regulation (EU) 2017/745 on medical devices.

Upplands Väsby, 2023-05-11



Henric Karsk
CEO

*First version of EU Declaration of Conformity (MDR) issued year 2021.
TF35_DoC_EN_2021-05-18*

Technical File TF35

List of item numbers

Device Group: X-ray holders

Doc Ref: TF35_List of item numbers

Revision: 12

Pgs: 1

TrollByte EZSoft & Lynx

Basic UDI-DI (GMN): 731023999511AP

REF/Catalogue number	Note	Model	UDI-DI (GTIN)
15500510		EzSoft #1	17310230004922
15500520		EzSoft #2	17310230004946
15500620		EzSoft #2 (Wave)	17310230006674
15500515		EZSoft #1,5	17310230004939
1541245001		Lynx Blue #1	17310230004045
1541315002		Lynx Blue #2	17310230004052
1543405001		Lynx Yellow #1	17310230004069
1543415002		Lynx Yellow #2	17310230004076

TrollByte Kimera

Basic UDI-DI (GMN): 731023999511AP

REF/Catalogue number	Note	Model	UDI-DI (GTIN)
1570312406	Kit	3106/2406	17310230005257
1570332405	Kit	3305/2405	17310230005271
1570332406	Kit	3306/2406	17310230005288
1570372405	Kit	3705/2405	17310230005295
1570372406	Kit	3706/2406	17310230005301
1570372407	Kit	3707/2407	17310230005318
1570372415	Kit	3705c/2405c	17310230005325
1570372605	Kit	3705/2605	17310230005332
1570372607	Kit	3707/2607	17310230005349
1570382503	Kit	3803/2503	17310230005356
1570382504	Kit	3804/2504	17310230005363
1570382904	Kit	3804/2904	17310230005370
1570392405	Kit	3905/2405	17310230005387
1570392406	Kit	3906/2406	17310230005394
1570392605	Kit	3905/2605	17310230005400
1570392607	Kit	3907/2607	17310230005417
1570392617	Kit	3905c/2607	17310230005424
1570392905	Kit	3905/2905	17310230005431
1570392914	Kit	3904c/2904c	17310230005448
1570393105	Kit	3905/3105	17310230005455
1570393107	Kit	3907/3107	17310230005462
1570393305	Kit	3905/3305	17310230005479

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1570392907	Kit	3907/2907	17310230021172
1570412405	Kit	4105/2405	17310230005486
1570412407	Kit	4107/2407	17310230005493
1570412605	Kit	4105/2605	17310230005509
1570412905	Kit	4105/2905	17310230005516
1570412907	Kit	4107/2907	17310230005523
1570413105	Kit	4105/3105	17310230005530
1570413115	Kit	4105c/3105	17310230005547
1570432905	Kit	4305/2905	17310230005554
1570432907	Kit	4307/2907	17310230005561
1570433103	Kit	4303/3103	17310230005578
1570433104	Kit	4304/3104	17310230005585
1570433105	Kit	4305/3105	17310230005127
1570433106	Kit	4306/3106	17310230005134
1570433113	Kit	4303c/3103c	17310230005592
1570433305	Kit	4305/3305	17310230005608
1570433307	Kit	4307/3307	17310230005615
1570382905	Kit	3803/2905	17310230020144
1570433306	Kit	4306/3306	17310230021257
1570392606	Kit	3906/2606	17310230021264
1570413104	Kit	4104/3104	17310230021400
1571330603		Blue 3306	17310230021271
1571260603		Blue 2606	17310230021295
1571240503		Blue 2405	17310230005639
1571240513		Blue 2405c	17310230005646
1571240603		Blue 2406	17310230005653
1571240703		Blue 2407	17310230005660
1571250303		Blue 2503	17310230005677
1571250403		Blue 2504	17310230005684
1571260503		Blue 2605	17310230005691
1571260703		Blue 2607	17310230005707
1571290403		Blue 2904	17310230005714
1571290503		Blue 2905	17310230005721
1571290703		Blue 2907	17310230005738
1571310303		Blue 3103	17310230005745
1571310313		Blue 3103c	17310230005752
1571310403		Blue 3104	17310230005769
1571310503		Blue 3105	17310230005141
1571310603		Blue 3106	17310230005158
1571310703		Blue 3107	17310230005776
1571330503		Blue 3305	17310230005783
1571330703		Blue 3307	17310230005790
1572330603		Red 3306	17310230021288
1572260603		Red 2606	17310230021301
1572240503		Red 2405	17310230005813

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1572240513		Red 2405c	17310230005820
1572240603		Red 2406	17310230005837
1572240703		Red 2407	17310230005844
1572250303		Red 2503	17310230005851
1572250403		Red 2504	17310230005868
1572260503		Red 2605	17310230005875
1572260703		Red 2607	17310230005882
1572290403		Red 2904	17310230005899
1572290503		Red 2905	17310230005905
1572290703		Red 2907	17310230005912
1572310303		Red 3103	17310230005929
1572310313		Red 3103c	17310230005936
1572310403		Red 3104	17310230005943
1572310503		Red 3105	17310230005165
1572310603		Red 3106	17310230005172
1572310703		Red 3107	17310230005950
1572330503		Red 3305	17310230005967
1572330703		Red 3307	17310230005974
1573310503		Yellow 3105	17310230006001
1573310603		Yellow 3106	17310230006018
1573330503		Yellow 3305	17310230006025
1573330603		Yellow 3306	17310230006247
1573370503		Yellow 3705	17310230006032
1573370513		Yellow 3705c	17310230006049
1573370603		Yellow 3706	17310230006056
1573370703		Yellow 3707	17310230006063
1573380303		Yellow 3803	17310230006070
1573380403		Yellow 3804	17310230006087
1573390413		Yellow 3904c	17310230006094
1573390503		Yellow 3905	17310230006100
1573390513		Yellow 3905c	17310230006117
1573390603		Yellow 3906	17310230006124
1573390703		Yellow 3907	17310230006131
1573410503		Yellow 4105	17310230006148
1573410513		Yellow 4105c	17310230006155
1573410703		Yellow 4107	17310230006162
1573430303		Yellow 4303	17310230006179
1573430313		Yellow 4303c	17310230006186
1573430403		Yellow 4304	17310230006193
1573430503		Yellow 4305	17310230005189
1573430603		Yellow 4306	17310230005196
1573430703		Yellow 4307	17310230005202
1570410403		Yellow 4104	17310230021417
1574312405		Endo 3105/2405	17310230006254
1574312406		Endo 3106/2406	17310230006261

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1574332405		Endo 3305/2405	17310230006285
1574372405		Endo 3705/2405	17310230006292
1574372406		Endo 3706/2406	17310230006308
1574372407		Endo 3707/2407	17310230006315
1574372415		Endo 3705c/2405c	17310230006322
1574372605		Endo 3705/2605	17310230006346
1574372607		Endo 3707/2607	17310230006346
1574382503		Endo 3803/2503	17310230006360
1574382504		Endo 3804/2504	17310230006360
1574382514		Endo 3804/2504c	17310230006377
1574382904		Endo 3804/2904	17310230006384
1574382905		Endo 3803/2905	17310230006391
1574392405		Endo 3905/2405	17310230006407
1574392406		Endo 3906/2406	17310230006414
1574392605		Endo 3905/2605	17310230006421
1574392607		Endo 3907/2607	17310230006438
1574392617		Endo 3905C/2607	17310230006445
1574392905		Endo 3905/2905	17310230006452
1574392914		Endo 3904C/2904C	17310230006469
1574393105		Endo 3905/3105	17310230006476
1574392907		Endo 3907/2907	17310230021165
1574393107		Endo 3907/3107	17310230006483
1574393305		Endo 3905/3305	17310230006490
1574412405		Endo 4105/2405	17310230006506
1574412407		Endo 4107/2407	17310230006513
1574412605		Endo 4105/2605	17310230006520
1574412905		Endo 4105/2905	17310230006537
1574412907		Endo 4107/2907	17310230006544
1574413105		Endo 4105/3105	17310230006551
1574413115		Endo 4105C/3105C	17310230006568
1574432905		Endo 4305/2905	17310230006575
1574432907		Endo 4307/2907	17310230006582
1574433103		Endo 4303/3103	17310230006599
1574433104		Endo 4304/3104	17310230006605
1574433105		Endo 4305/3105	17310230006612
1574433106		Endo 4306/3106	17310230006629
1574433113		Endo 4303C/3103C	17310230006636
1574433305		Endo 4305/3305	17310230006643
1574433307		Endo 4307/3307	17310230006650
1576033253		Image Plate Kit #0	17310230006827
1576038253		Image Plate Kit #0+	17310230006834
1576043253		Image Plate Kit #1	17310230006841
1576043313		Image Plate Kit #2	17310230006858
1573125033		Image Plate Blue #1	17310230019964
1573125233		Image Plate Blue #0	17310230019971

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1576131033		Image Plate Blue #2	17310230006889
1576225033		Image Plate Red #1	17310230006896
1576225233		Image Plate Red #0	17310230006902
1576231033		Image Plate Red #2	17310230006919
1576333053		Image Plate Yellow #0	17310230006926
1576338033		Image Plate Yellow #0+	17310230006933
1576343033		Image Plate Yellow #2	17310230006940
1576433253		Image Plate Yellow #1	17310230006964
1576443253		Image Plate Endo #1	17310230006971
1576443313		Image Plate Endo #2	17310230006988
1579001001		Aiming Ring	17310230006216
1579002003		Bite Block, 3 pcs	17310230006223
1579402002		Endo Block	17310230006667
1575038253		Film Kit #0	17310230020069
1575043253		Film Kit #1	17310230020076
1575043313		Film Kit #2	17310230020083
1575125033		Film Blue #1	17310230020090
1575125233		Film Blue #0	17310230020106
1575131033		Film Blue #2	17310230020113
1575225233		Film Red #0	17310230020120
1575231033		Film Red #2	17310230007268
1575225033		Film Red #1	17310230020052
1575338033		Film Yellow #0	17310230020137
1575343033		Film Yellow #2	17310230020199
1570413006		Kit 4106/3006	17310230020250
1573410603		Yellow 4106	17310230020267
1572300603		Red 3006	17310230020274
1571300603		Blue 3006	17310230020281
1570382406		Kit 3806/2406	17310230020298
1573380603		Yellow 3806	17310230020304
30029113	Planmeca	TrollByte Kimera Kit 3306/2406	17310230019988
30029114	Planmeca	TrollByte Kimera Kit 3906/2406	17310230019995
30029115	Planmeca	TrollByte Kimera Kit 4306/3106	17310230020007
13332406	Kavo	TrollByte Kimera Kit 3306/2406	17310230021226
13392406	Kavo	TrollByte Kimera Kit 3906/2406	17310230021233
13433106	Kavo	TrollByte Kimera Kit 4306/3106	17310230021240

Revision history

Revision/Date	Issuer	Reason for change/update
12/ 2023-05-11	Sandra Peiponen, Product Manager <i>Sandra Peiponen</i>	CH-23-027