

EU Technical Documentation Assessment Certificate

Certificate no.
20004GB450240516

Final Assessment Report no.
20004AU03F

Effective date
2024-05-16

Expiry date
2026-08-04

This is to certify that
Medical devices listed on the following pages

Manufactured by

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany

SRN: DE-MF-000005504

Have been assessed and found to comply with respect to

**Technical Documentation Assessment as described in Annex IX,
Chapter II of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certificate assumes that DNV MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by DNV MEDCERT.

For conditions or for limitations to the validity refer to the relevant final assessment report. Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s), are recorded in the relevant reports. For placing on the market of the medical devices covered by this certificate, an additional EU Quality Management System Certificate according to Annex IX, Chapters I and III of Regulation (EU) 2017/745 is required.

Place and date
Hamburg, 2024-05-16



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany


Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

Preceding certificate

Certificate no.	Issue date	Identification of changes
20004GB450210805	2021-08-05	CN 33, WO-010496, additional REF numbers

Products covered by this certificate

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016652Y
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH091D	SC/MSC BIOLOX DELTA INS.28MM 44/46 SYM.
NH092D	SC/MSC BIOLOX DELTA INS.28MM 48/50 SYM.
NH093D	SC/MSC BIOLOX DELTA INS.28MM 52/54 SYM.
NH102D	SC/MSC BIOLOX DELTA INS.32MM 48/50 SYM.
NH103D	SC/MSC BIOLOX DELTA INS.32MM 52/54 SYM.
NH104D	SC/MSC BIOLOX DELTA INS.32MM 56/58 SYM.
NH105D	SC/MSC BIOLOX DELTA INS.32MM 60/62 SYM.
NH106D	SC/MSC BIOLOX DELTA INS.32MM 64-68 SYM.
NH109D	SC/MSC BIOLOX DELTA INS.36MM 56/58 SYM.
NH110D	SC/MSC BIOLOX DELTA INS.36MM 60/62 SYM.
NH111D	SC/MSC BIOLOX DELTA INS.36MM 64-68 SYM.
NH521D	DC BIOLOX DELTA INSERT 28MM 44/46 SYM.
NH522D	DC BIOLOX DELTA INSERT 32MM 48/50 SYM.
NH526D	DC BIOLOX DELTA INSERT 36MM 52/54 SYM.
NH527D	DC BIOLOX DELTA INSERT 36MM 56-62 SYM.
NH528D	DC BIOLOX DELTA INSERT 36MM 64-68 SYM.
NV089D	BIOLOX DELTA INSERT C 28MM SYM.
NV090D	BIOLOX DELTA INSERT D 28MM SYM.
NV091D	BIOLOX DELTA INSERT E 28MM SYM.
NV092D	BIOLOX DELTA INSERT F 28MM SYM.
NV093D	BIOLOX DELTA INSERT G 28MM SYM.
NV094D	BIOLOX DELTA INSERT H 28MM SYM.
NV101D	BIOLOX DELTA INSERT E 32MM SYM.
NV102D	BIOLOX DELTA INSERT F 32MM SYM.
NV103D	BIOLOX DELTA INSERT G 32MM SYM.
NV104D	BIOLOX DELTA INSERT H 32MM SYM.
NV105D	BIOLOX DELTA INSERT I 32MM SYM.
NV106D	BIOLOX DELTA INSERT J 32MM SYM.
NV107D	BIOLOX DELTA INSERT K 32MM SYM.
NV113D	BIOLOX DELTA INSERT G 36MM SYM.
NV114D	BIOLOX DELTA INSERT H 36MM SYM.
NV115D	BIOLOX DELTA INSERT I 36MM SYM.
NV116D	BIOLOX DELTA INSERT J 36MM SYM.
NV117D	BIOLOX DELTA INSERT K 36MM SYM.
NV125D	BIOLOX DELTA INSERT I 40MM SYM.



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NV126D	BIOLOX DELTA INSERT J 40MM SYM.
NV127D	BIOLOX DELTA INSERT K 40MM SYM.

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000166632
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NJ101D	BIOLOX DELTA PROSTHESIS HEAD 8/10 28MM S
NJ102D	BIOLOX DELTA PROSTHESIS HEAD 8/10 28MM M
NJ103D	BIOLOX DELTA PROSTHESIS HEAD 8/10 28MM L
NJ106D	BIOLOX DELTA PROSTHESIS HEAD 8/10 32MM S
NJ107D	BIOLOX DELTA PROSTHESIS HEAD 8/10 32MM M
NJ108D	BIOLOX DELTA PROSTHESIS HEAD 8/10 32MM L
NJ116D	BIOLOX DELTA PROSTH.HEAD 8/10 36MM S
NJ117D	BIOLOX DELTA PROSTH.HEAD 8/10 36MM M
NJ118D	BIOLOX DELTA PROSTH.HEAD 8/10 36MM L
NJ119D	BIOLOX DELTA PROSTH.HEAD 8/10 36MM XL
NK460D	BIOLOX DELTA PROSTH.HEAD 12/14 28MM S
NK461D	BIOLOX DELTA PROSTH.HEAD 12/14 28MM M
NK462D	BIOLOX DELTA PROSTH.HEAD 12/14 28MM L
NK560D	BIOLOX DELTA PROSTH.HEAD 12/14 32MM S
NK561D	BIOLOX DELTA PROSTH.HEAD 12/14 32MM M
NK562D	BIOLOX DELTA PROSTH.HEAD 12/14 32MM L
NK563D	BIOLOX DELTA PROSTH.HEAD 12/14 32MM XL
NK650D	BIOLOX DELTA PROSTH.HEAD 12/14 36MM S
NK651D	BIOLOX DELTA PROSTH.HEAD 12/14 36MM M
NK652D	BIOLOX DELTA PROSTH.HEAD 12/14 36MM L
NK653D	BIOLOX DELTA PROSTH.HEAD 12/14 36MM XL
NK750D	BIOLOX DELTA PROSTH.HEAD 12/14 40MM S
NK751D	BIOLOX DELTA PROSTH.HEAD 12/14 40MM M
NK752D	BIOLOX DELTA PROSTH.HEAD 12/14 40MM L
NK753D	BIOLOX DELTA PROSTH.HEAD 12/14 40MM XL

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000166734
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NJ081	BIOLOX PROSTHESIS HEAD 8/10 22.2MM S
NJ082	BIOLOX PROSTHESIS HEAD 8/10 22.2MM M
NJ091	BIOLOX PROSTHESIS HEAD 8/10 26MM S
NJ092	BIOLOX PROSTHESIS HEAD 8/10 26MM M
NJ093	BIOLOX PROSTHESIS HEAD 8/10 26MM L
NK461	BIOLOX PROSTHESIS HEAD 12/14 28MM M
NK462	BIOLOX PROSTHESIS HEAD 12/14 28MM L
NK560	BIOLOX PROSTHESIS HEAD 12/14 32MM S



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NK561	BIOLOX PROSTHESIS HEAD 12/14 32MM M
NK562	BIOLOX PROSTHESIS HEAD 12/14 32MM L
NK650	BIOLOX PROSTHESIS HEAD 12/14 36MM S
NK651	BIOLOX PROSTHESIS HEAD 12/14 36MM M
NK652	BIOLOX PROSTHESIS HEAD 12/14 36MM L
NK860	BIOLOX PROSTHESIS HEAD 12/14 26MM S
NK861	BIOLOX PROSTHESIS HEAD 12/14 26MM M
NK862	BIOLOX PROSTHESIS HEAD 12/14 26MM L

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000166836
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NK435	BIOLOX DELTA REVISION HEAD 12/14 28MM S
NK436	BIOLOX DELTA REVISION HEAD 12/14 28MM M
NK437	BIOLOX DELTA REVISION HEAD 12/14 28MM L
NK438	BIOLOX DELTA REVISION HEAD 12/14 28MM XL
NK535	BIOLOX DELTA REVISION HEAD 12/14 32MM S
NK536	BIOLOX DELTA REVISION HEAD 12/14 32MM M
NK537	BIOLOX DELTA REVISION HEAD 12/14 32MM L
NK538	BIOLOX DELTA REVISION HEAD 12/14 32MM XL
NK635	BIOLOX DELTA REVISION HEAD 12/14 36MM S
NK636	BIOLOX DELTA REVISION HEAD 12/14 36MM M
NK637	BIOLOX DELTA REVISION HEAD 12/14 36MM L
NK638	BIOLOX DELTA REVISION HEAD 12/14 36MM XL

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000166938
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NJ435T	SLEEVE 8/10 S F/BIOLOX REVISION HEAD
NJ436T	SLEEVE 8/10 M F/BIOLOX REVISION HEAD
NJ437T	SLEEVE 8/10 L F/BIOLOX REVISION HEAD
NJ438T	SLEEVE 8/10 XL F/BIOLOX REVISION HEAD

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016702R
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NK019K	BIPOLAR CUP ID22.2MM OD39MM SELF-CENTER.
NK020K	BIPOLAR CUP ID22.2MM OD40MM SELF-CENTER.
NK021K	BIPOLAR CUP ID22.2MM OD41MM SELF-CENTER.
NK022K	BIPOLAR CUP ID22.2MM OD42MM SELF-CENTER.
NK023K	BIPOLAR CUP ID22.2MM OD43MM SELF-CENTER.

NK024K	BIPOLAR CUP ID22.2MM OD44MM SELF-CENTER.
NK025K	BIPOLAR CUP ID22.2MM OD45MM SELF-CENTER.
NK026K	BIPOLAR CUP ID22.2MM OD46MM SELF-CENTER.
NK027K	BIPOLAR CUP ID22.2MM OD47MM SELF-CENTER.
NK028K	BIPOLAR CUP ID22.2MM OD48MM SELF-CENTER.
NK029K	BIPOLAR CUP ID22.2MM OD49MM SELF-CENTER.
NK030K	BIPOLAR CUP ID22.2MM OD50MM SELF-CENTER.
NK031K	BIPOLAR CUP ID22.2MM OD51MM SELF-CENTER.
NK032K	BIPOLAR CUP ID22.2MM OD52MM SELF-CENTER.
NK033K	BIPOLAR CUP ID22.2MM OD53MM SELF-CENTER.
NK034K	BIPOLAR CUP ID22.2MM OD54MM SELF-CENTER.
NK035K	BIPOLAR CUP ID22.2MM OD55MM SELF-CENTER.
NK047K	BIPOLAR CUP ID28MM OD47MM SELF-CENTERING
NK048K	BIPOLAR CUP ID28MM OD48MM SELF-CENTERING
NK049K	BIPOLAR CUP ID28MM OD49MM SELF-CENTERING
NK050K	BIPOLAR CUP ID28MM OD50MM SELF-CENTERING
NK051K	BIPOLAR CUP ID28MM OD51MM SELF-CENTERING
NK052K	BIPOLAR CUP ID28MM OD52MM SELF-CENTERING
NK053K	BIPOLAR CUP ID28MM OD53MM SELF-CENTERING
NK054K	BIPOLAR CUP ID28MM OD54MM SELF-CENTERING
NK055K	BIPOLAR CUP ID28MM OD55MM SELF-CENTERING
NK056K	BIPOLAR CUP ID28MM OD56MM SELF-CENTERING
NK057K	BIPOLAR CUP ID28MM OD57MM SELF-CENTERING
NK058K	BIPOLAR CUP ID28MM OD58MM SELF-CENTERING
NK059K	BIPOLAR CUP ID28MM OD59MM SELF-CENTERING
NK060K	BIPOLAR CUP ID28MM OD60MM SELF-CENTERING
NK291K	BIPOLAR CUP ID26MM OD41MM SELF-CENTERING
NK292K	BIPOLAR CUP ID26MM OD42MM SELF-CENTERING
NK293K	BIPOLAR CUP ID26MM OD43MM SELF-CENTERING
NK294K	BIPOLAR CUP ID26MM OD44MM SELF-CENTERING
NK295K	BIPOLAR CUP ID26MM OD45MM SELF-CENTERING
NK296K	BIPOLAR CUP ID26MM OD46MM SELF-CENTERING
NK297K	BIPOLAR CUP ID26MM OD47MM SELF-CENTERING
NK298K	BIPOLAR CUP ID26MM OD48MM SELF-CENTERING
NK299K	BIPOLAR CUP ID26MM OD49MM SELF-CENTERING
NK300K	BIPOLAR CUP ID26MM OD50MM SELF-CENTERING
NK301K	BIPOLAR CUP ID26MM OD51MM SELF-CENTERING
NK302K	BIPOLAR CUP ID26MM OD52MM SELF-CENTERING
NK303K	BIPOLAR CUP ID26MM OD53MM SELF-CENTERING
NK304K	BIPOLAR CUP ID26MM OD54MM SELF-CENTERING
NK305K	BIPOLAR CUP ID26MM OD55MM SELF-CENTERING



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016712T
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NK019S	BIPOLAR CUP ID22.2MM OD39MM SELF-CENTER.
NK020S	BIPOLAR CUP ID22.2MM OD40MM SELF-CENTER.
NK021S	BIPOLAR CUP ID22.2MM OD41MM SELF-CENTER.
NK022S	BIPOLAR CUP ID22.2MM OD42MM SELF-CENTER.
NK023S	BIPOLAR CUP ID22.2MM OD43MM SELF-CENTER.
NK024S	BIPOLAR CUP ID22.2MM OD44MM SELF-CENTER.
NK025S	BIPOLAR CUP ID22.2MM OD45MM SELF-CENTER.
NK026S	BIPOLAR CUP ID22.2MM OD46MM SELF-CENTER.
NK027S	BIPOLAR CUP ID22.2MM OD47MM SELF-CENTER.
NK028S	BIPOLAR CUP ID22.2MM OD48MM SELF-CENTER.
NK029S	BIPOLAR CUP ID22.2MM OD49MM SELF-CENTER.
NK030S	BIPOLAR CUP ID22.2MM OD50MM SELF-CENTER.
NK031S	BIPOLAR CUP ID22.2MM OD51MM SELF-CENTER.
NK032S	BIPOLAR CUP ID22.2MM OD52MM SELF-CENTER.
NK033S	BIPOLAR CUP ID22.2MM OD53MM SELF-CENTER.
NK034S	BIPOLAR CUP ID22.2MM OD54MM SELF-CENTER.
NK035S	BIPOLAR CUP ID22.2MM OD55MM SELF-CENTER.
NK043S	BIPOLAR CUP ID28MM OD43MM SELF-CENTERING
NK044S	BIPOLAR CUP ID28MM OD44MM SELF-CENTERING
NK045S	BIPOLAR CUP ID28MM OD45MM SELF-CENTERING
NK046S	BIPOLAR CUP ID28MM OD46MM SELF-CENTERING
NK047S	BIPOLAR CUP ID28MM OD47MM SELF-CENTERING
NK048S	BIPOLAR CUP ID28MM OD48MM SELF-CENTERING
NK049S	BIPOLAR CUP ID28MM OD49MM SELF-CENTERING
NK050S	BIPOLAR CUP ID28MM OD50MM SELF-CENTERING
NK051S	BIPOLAR CUP ID28MM OD51MM SELF-CENTERING
NK052S	BIPOLAR CUP ID28MM OD52MM SELF-CENTERING
NK053S	BIPOLAR CUP ID28MM OD53MM SELF-CENTERING
NK054S	BIPOLAR CUP ID28MM OD54MM SELF-CENTERING
NK055S	BIPOLAR CUP ID28MM OD55MM SELF-CENTERING

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016722V
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NK324	ISOCER PROSTHESIS HEAD 12/14 28MM S
NK325	ISOCER PROSTHESIS HEAD 12/14 28MM M
NK326	ISOCER PROSTHESIS HEAD 12/14 28MM L
NK424	ISOCER PROSTHESIS HEAD 12/14 32MM S
NK425	ISOCER PROSTHESIS HEAD 12/14 32MM M
NK426	ISOCER PROSTHESIS HEAD 12/14 32MM L



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NK427	ISOCER PROSTHESIS HEAD 12/14 32MM XL
NK524	ISOCER PROSTHESIS HEAD 12/14 36MM S
NK525	ISOCER PROSTHESIS HEAD 12/14 36MM M
NK526	ISOCER PROSTHESIS HEAD 12/14 36MM L
NK527	ISOCER PROSTHESIS HEAD 12/14 36MM XL

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016732X
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NJ111K	ISODUR PROSTHESIS HEAD 8/10 22.2MM S
NJ112K	ISODUR PROSTHESIS HEAD 8/10 22.2MM M
NJ113K	ISODUR PROSTHESIS HEAD 8/10 22.2MM L
NJ121K	ISODUR PROSTHESIS HEAD 8/10 26MM S
NJ122K	ISODUR PROSTHESIS HEAD 8/10 26MM M
NJ123K	ISODUR PROSTHESIS HEAD 8/10 26MM L
NJ124K	ISODUR PROSTHESIS HEAD 8/10 26MM XL
NJ126K	ISODUR PROSTHESIS HEAD 8/10 32MM S
NJ127K	ISODUR PROSTHESIS HEAD 8/10 32MM M
NJ128K	ISODUR PROSTHESIS HEAD 8/10 32MM L
NJ129K	ISODUR PROSTHESIS HEAD 8/10 32MM XL
NJ131K	ISODUR PROSTHESIS HEAD 8/10 28MM S
NJ132K	ISODUR PROSTHESIS HEAD 8/10 28MM M
NJ133K	ISODUR PROSTHESIS HEAD 8/10 28MM L
NJ134K	ISODUR PROSTHESIS HEAD 8/10 28MM XL
NK330K	ISODUR PROSTHESIS HEAD 12/14 22.2MM M
NK331K	ISODUR PROSTHESIS HEAD 12/14 22.2MM L
NK389K	ISODUR PROSTHESIS HEAD 12/14 26MM S
NK390K	ISODUR PROSTHESIS HEAD 12/14 26MM M
NK391K	ISODUR PROSTHESIS HEAD 12/14 26MM L
NK392K	ISODUR PROSTHESIS HEAD 12/14 26MM XL
NK429K	ISODUR PROSTHESIS HEAD 12/14 28MM S
NK430K	ISODUR PROSTHESIS HEAD 12/14 28MM M
NK431K	ISODUR PROSTHESIS HEAD 12/14 28MM L
NK432K	ISODUR PROSTHESIS HEAD 12/14 28MM XL
NK433K	ISODUR PROSTHESIS HEAD 12/14 28MM XXL
NK529K	ISODUR PROSTHESIS HEAD 12/14 32MM S
NK530K	ISODUR PROSTHESIS HEAD 12/14 32MM M
NK531K	ISODUR PROSTHESIS HEAD 12/14 32MM L
NK532K	ISODUR PROSTHESIS HEAD 12/14 32MM XL
NK533K	ISODUR PROSTHESIS HEAD 12/14 32MM XXL
NK669K	ISODUR PROSTHESIS HEAD 12/14 36MM S
NK670K	ISODUR PROSTHESIS HEAD 12/14 36MM M
NK671K	ISODUR PROSTHESIS HEAD 12/14 36MM L
NK672K	ISODUR PROSTHESIS HEAD 12/14 36MM XL
NK673K	ISODUR PROSTHESIS HEAD 12/14 36MM XXL



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NK769K	ISODUR PROSTHESIS HEAD 12/14 40MM S
NK770K	ISODUR PROSTHESIS HEAD 12/14 40MM M
NK771K	ISODUR PROSTHESIS HEAD 12/14 40MM L
NK772K	ISODUR PROSTHESIS HEAD 12/14 40MM XL
NK773K	ISODUR PROSTHESIS HEAD 12/14 40MM XXL

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016742Z
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH946	ISOFAR PE-CUP 28MM 46MM STANDARD
NH947	ISOFAR PE-CUP 28MM 46MM ANTILUX
NH948	ISOFAR PE-CUP 28MM 48MM STANDARD
NH949	ISOFAR PE-CUP 28MM 48MM ANTILUX
NH951	ISOFAR PE-CUP 28MM 50MM ANTILUX
NH953	ISOFAR PE-CUP 28MM 52MM ANTILUX
NH955	ISOFAR PE-CUP 28MM 54MM ANTILUX
NH957	ISOFAR PE-CUP 28MM 56MM ANTILUX
NH959	ISOFAR PE-CUP 28MM 58MM ANTILUX
NH961	ISOFAR PE-CUP 28MM 60MM ANTILUX
NH963	ISOFAR PE-CUP 28MM 62MM ANTILUX
NH968	ISOFAR PE-CUP 32MM 48MM STANDARD
NH969	ISOFAR PE-CUP 32MM 48MM ANTILUX
NH970	ISOFAR PE-CUP 32MM 50MM STANDARD
NH971	ISOFAR PE-CUP 32MM 50MM ANTILUX
NH972	ISOFAR PE-CUP 32MM 52MM STANDARD
NH973	ISOFAR PE-CUP 32MM 52MM ANTILUX
NH974	ISOFAR PE-CUP 32MM 54MM STANDARD
NH975	ISOFAR PE-CUP 32MM 54MM ANTILUX
NH976	ISOFAR PE-CUP 32MM 56MM STANDARD
NH977	ISOFAR PE-CUP 32MM 56MM ANTILUX
NH978	ISOFAR PE-CUP 32MM 58MM STANDARD
NH979	ISOFAR PE-CUP 32MM 58MM ANTILUX
NH980	ISOFAR PE-CUP 32MM 60MM STANDARD
NH981	ISOFAR PE-CUP 32MM 60MM ANTILUX
NH982	ISOFAR PE-CUP 32MM 62MM STANDARD
NH983	ISOFAR PE-CUP 32MM 62MM ANTILUX
NK810	PE-CUP 22.2MM 40MM
NK812	PE-CUP 22.2MM 42MM
NK842	PE-CUP 28MM 42MM
NK844	PE-CUP 28MM 44MM
NK846	PE-CUP 28MM 46MM
NK848	PE-CUP 28MM 48MM
NK850	PE-CUP 28MM 50MM
NK852	PE-CUP 28MM 52MM
NK854	PE-CUP 28MM 54MM



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NK856	PE-CUP 28MM 56MM
NK858	PE-CUP 28MM 58MM
NK870	PE-CUP 28MM 60MM
NK872	PE-CUP 28MM 62MM
NK874	PE-CUP 28MM 64MM
NK946	PE-CUP 32MM 46MM
NK948	PE-CUP 32MM 48MM
NK950	PE-CUP 32MM 50MM
NK952	PE-CUP 32MM 52MM
NK954	PE-CUP 32MM 54MM
NK956	PE-CUP 32MM 56MM
NK958	PE-CUP 32MM 58MM
NK960	PE-CUP 32MM 60MM
NK962	PE-CUP 32MM 62MM
NK964	PE-CUP 32MM 64MM

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000167533
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NC444T	PLASMACUP SC PLASMAPORE-µCAP SIZE 44MM
NC446T	PLASMACUP SC PLASMAPORE-µCAP SIZE 46MM
NC448T	PLASMACUP SC PLASMAPORE-µCAP SIZE 48MM
NC450T	PLASMACUP SC PLASMAPORE-µCAP SIZE 50MM
NC452T	PLASMACUP SC PLASMAPORE-µCAP SIZE 52MM
NC454T	PLASMACUP SC PLASMAPORE-µCAP SIZE 54MM
NC456T	PLASMACUP SC PLASMAPORE-µCAP SIZE 56MM
NC458T	PLASMACUP SC PLASMAPORE-µCAP SIZE 58MM
NC460T	PLASMACUP SC PLASMAPORE-µCAP SIZE 60MM
NC462T	PLASMACUP SC PLASMAPORE-µCAP SIZE 62MM

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000167635
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH040T	PLASMACUP SC SIZE 40MM
NH042T	PLASMACUP SC SIZE 42MM
NH044T	PLASMACUP SC SIZE 44MM
NH046T	PLASMACUP SC SIZE 46MM
NH048T	PLASMACUP SC SIZE 48MM
NH050T	PLASMACUP SC SIZE 50MM
NH052T	PLASMACUP SC SIZE 52MM
NH054T	PLASMACUP SC SIZE 54MM
NH056T	PLASMACUP SC SIZE 56MM
NH058T	PLASMACUP SC SIZE 58MM



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NH060T	PLASMACUP SC SIZE 60MM
NH062T	PLASMACUP SC SIZE 62MM
NH064T	PLASMACUP SC SIZE 64MM
NH066T	PLASMACUP SC SIZE 66MM
NH068T	PLASMACUP SC SIZE 68MM
NH140T	PLASMACUP MSC SIZE 40MM
NH142T	PLASMACUP MSC SIZE 42MM
NH144T	PLASMACUP MSC SIZE 44MM
NH146T	PLASMACUP MSC SIZE 46MM
NH148T	PLASMACUP MSC SIZE 48MM
NH150T	PLASMACUP MSC SIZE 50MM
NH152T	PLASMACUP MSC SIZE 52MM
NH154T	PLASMACUP MSC SIZE 54MM
NH156T	PLASMACUP MSC SIZE 56MM
NH158T	PLASMACUP MSC SIZE 58MM
NH160T	PLASMACUP MSC SIZE 60MM
NH162T	PLASMACUP MSC SIZE 62MM
NH164T	PLASMACUP MSC SIZE 64MM
NH166T	PLASMACUP MSC SIZE 66MM
NH168T	PLASMACUP MSC SIZE 68MM
NH344T	PLASMACUP NSC SIZE 44MM
NH346T	PLASMACUP NSC SIZE 46MM
NH348T	PLASMACUP NSC SIZE 48MM
NH350T	PLASMACUP NSC SIZE 50MM
NH352T	PLASMACUP NSC SIZE 52MM
NH354T	PLASMACUP NSC SIZE 54MM
NH356T	PLASMACUP NSC SIZE 56MM
NH358T	PLASMACUP NSC SIZE 58MM
NH360T	PLASMACUP NSC SIZE 60MM
NH362T	PLASMACUP NSC SIZE 62MM
NH544T	PLASMACUP DC SIZE 44MM
NH546T	PLASMACUP DC SIZE 46MM
NH548T	PLASMACUP DC SIZE 48MM
NH550T	PLASMACUP DC SIZE 50MM
NH552T	PLASMACUP DC SIZE 52MM
NH554T	PLASMACUP DC SIZE 54MM
NH556T	PLASMACUP DC SIZE 56MM
NH558T	PLASMACUP DC SIZE 58MM
NH560T	PLASMACUP DC SIZE 60MM
NH562T	PLASMACUP DC SIZE 62MM
NH564T	PLASMACUP DC SIZE 64MM
NH566T	PLASMACUP DC SIZE 66MM
NH568T	PLASMACUP DC SIZE 68MM



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000167737
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH652D	PLASMACUP DELTA 36MM SIZE 52MM
NH654D	PLASMACUP DELTA 36MM SIZE 54MM

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000167839
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH632D	PLC-DELTA CERAMICS INSERT 32MM SZ.44/46
NH636D	PLC-DELTA CERAMICS INSERT 36MM SZ.48
NH637D	PLC-DELTA CERAMICS INSERT 36MM SZ.50-54

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016793B
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH407	PLC-DELTA PE-INSERT 28MM 44/46 POST.WALL
NH417	PLC-DELTA PE-INSERT 32MM 48MM POST.WALL
NH418	PLC-DELTA PE-INSERT 32MM 50-54 POST.WALL

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016802U
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH170	SC/MSC PE-INSERT 22.2MM 40/42 SYM.
NH171	SC/MSC PE-INSERT 22.2MM 44/46 SYM.
NH172	SC/MSC PE-INSERT 22.2MM 48/50 SYM.
NH181	SC/MSC PE-INSERT 26MM 44/46 SYM.
NH182	SC/MSC PE-INSERT 26MM 48/50 SYM.
NH191	SC/MSC PE-INSERT 28MM 44/46 SYM.
NH192	SC/MSC PE-INSERT 28MM 48/50 SYM.
NH193	SC/MSC PE-INSERT 28MM 52/54 SYM.
NH194	SC/MSC PE-INSERT 28MM 56/58 SYM.
NH195	SC/MSC PE-INSERT 28MM 60/62 SYM.
NH196	SC/MSC PE-INSERT 28MM 64-68 SYM.
NH202	SC/MSC PE-INSERT 32MM 48/50 SYM.
NH203	SC/MSC PE-INSERT 32MM 52/54 SYM.
NH204	SC/MSC PE-INSERT 32MM 56/58 SYM.
NH205	SC/MSC PE-INSERT 32MM 60/62 SYM.
NH206	SC/MSC PE-INSERT 32MM 64-68 SYM.



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NH300	SC/MSC PE-INSERT 22.2MM 40/42 POST.WALL
NH301	SC/MSC PE-INSERT 22.2MM 44/46 POST.WALL
NH302	SC/MSC PE-INSERT 22.2MM 48/50 POST.WALL
NH311	SC/MSC PE-INSERT 26MM 44/46 POST.WALL
NH312	SC/MSC PE-INSERT 26MM 48/50 POST.WALL
NH323	SC/MSC PE-INSERT 32MM 52/54 ASYM.
NH324	SC/MSC PE-INSERT 32MM 56/58 ASYM.
NH325	SC/MSC PE-INSERT 32MM 60/62 ASYM.
NH326	SC/MSC PE-INSERT 32MM 64-68 ASYM.
NH401	SC/MSC PE-INSERT 28MM 44/46 POST.WALL
NH402	SC/MSC PE-INSERT 28MM 48/50 POST.WALL
NH403	SC/MSC PE-INSERT 28MM 52/54 POST.WALL
NH404	SC/MSC PE-INSERT 28MM 56/58 POST.WALL
NH405	SC/MSC PE-INSERT 28MM 60/62 POST.WALL
NH406	SC/MSC PE-INSERT 28MM 64-68 POST.WALL
NH413	SC/MSC PE-INSERT 32MM 52/54 POST.WALL
NH414	SC/MSC PE-INSERT 32MM 56/58 POST.WALL
NH415	SC/MSC PE-INSERT 32MM 60/62 POST.WALL
NH416	SC/MSC PE-INSERT 32MM 64-68 POST.WALL
NH471	SC/MSC PE-INSERT 28MM 44/46 ASYM.
NH472	SC/MSC PE-INSERT 28MM 48/50 ASYM.
NH473	SC/MSC PE-INSERT 28MM 52/54 ASYM.
NH474	SC/MSC PE-INSERT 28MM 56/58 ASYM.
NH475	SC/MSC PE-INSERT 28MM 60/62 ASYM.
NH476	SC/MSC PE-INSERT 28MM 64-68 ASYM.

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016812W
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH191E	SC/MSC VITELENE INSERT 28MM 44/46 SYM.
NH202E	SC/MSC VITELENE INSERT 32MM 48/50 SYM.
NH203E	SC/MSC VITELENE INSERT 32MM 52/54 SYM.
NH204E	SC/MSC VITELENE INSERT 32MM 56/58 SYM.
NH205E	SC/MSC VITELENE INSERT 32MM 60/62 SYM.
NH206E	SC/MSC VITELENE INSERT 32MM 64-68 SYM.
NH209E	SC/MSC VITELENE INSERT 36MM 56/58 SYM.
NH210E	SC/MSC VITELENE INSERT 36MM 60/62 SYM.
NH211E	SC/MSC VITELENE INSERT 36MM 64-68 SYM.
NH401E	SC/MSC VITELENE INSERT 28MM 44/46 P.WALL
NH402E	SC/MSC VITELENE INSERT 28MM 48/50 P.WALL
NH413E	SC/MSC VITELENE INSERT 32MM 52/54 P.WALL
NH414E	SC/MSC VITELENE INSERT 32MM 56/58 P.WALL
NH415E	SC/MSC VITELENE INSERT 32MM 60/62 P.WALL
NH416E	SC/MSC VITELENE INSERT 32MM 64-68 P.WALL
NH501E	DC VITELENE INSERT 28MM 44/46 SYM.



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NH502E	DC VITELENE INSERT 32MM 48/50 SYM.
NH503E	DC VITELENE INSERT 32MM 52/54 SYM.
NH504E	DC VITELENE INSERT 32MM 56-62 SYM.
NH505E	DC VITELENE INSERT 32MM 64-68 SYM.
NH506E	DC VITELENE INSERT 36MM 52/54 SYM.
NH507E	DC VITELENE INSERT 36MM 56-62 SYM.
NH508E	DC VITELENE INSERT 36MM 64-68 SYM.
NH511E	DC VITELENE INSERT 28MM 44/46 POST.WALL
NH512E	DC VITELENE INSERT 32MM 48/50 POST.WALL
NH513E	DC VITELENE INSERT 32MM 52/54 POST.WALL
NH514E	DC VITELENE INSERT 32MM 56-62 POST.WALL
NH515E	DC VITELENE INSERT 32MM 64-68 POST.WALL

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016822Y
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NC340T	PLASMAFIT POLY CUP µCAP SIZE 40MM B
NC342T	PLASMAFIT POLY CUP µCAP SIZE 42MM C
NC344T	PLASMAFIT POLY CUP µCAP SIZE 44MM D
NC346T	PLASMAFIT POLY CUP µCAP SIZE 46MM E
NC348T	PLASMAFIT POLY CUP µCAP SIZE 48MM F
NC350T	PLASMAFIT POLY CUP µCAP SIZE 50MM G
NC352T	PLASMAFIT POLY CUP µCAP SIZE 52MM H
NC354T	PLASMAFIT POLY CUP µCAP SIZE 54MM I
NC356T	PLASMAFIT POLY CUP µCAP SIZE 56MM J
NC358T	PLASMAFIT POLY CUP µCAP SIZE 58MM K
NC360T	PLASMAFIT POLY CUP µCAP SIZE 60MM L
NC362T	PLASMAFIT POLY CUP µCAP SIZE 62MM M
NC740T	PLASMAFIT PLUS CUP µCAP SIZE 40MM A
NC742T	PLASMAFIT PLUS CUP µCAP SIZE 42MM B
NC744T	PLASMAFIT PLUS CUP µCAP SIZE 44MM C
NC746T	PLASMAFIT PLUS CUP µCAP SIZE 46MM D
NC748T	PLASMAFIT PLUS CUP µCAP SIZE 48MM E
NC750T	PLASMAFIT PLUS CUP µCAP SIZE 50MM F
NC752T	PLASMAFIT PLUS CUP µCAP SIZE 52MM G
NC754T	PLASMAFIT PLUS CUP µCAP SIZE 54MM H
NC756T	PLASMAFIT PLUS CUP µCAP SIZE 56MM I
NC758T	PLASMAFIT PLUS CUP µCAP SIZE 58MM J
NC760T	PLASMAFIT PLUS CUP µCAP SIZE 60MM J
NC762T	PLASMAFIT PLUS CUP µCAP SIZE 62MM J
NC764T	PLASMAFIT PLUS CUP µCAP SIZE 64MM K
NC766T	PLASMAFIT PLUS CUP µCAP SIZE 66MM K
NC768T	PLASMAFIT PLUS CUP µCAP SIZE 68MM K
NC770T	PLASMAFIT PLUS CUP µCAP SIZE 70MM K
NC840T	PLASMAFIT PLUS 3 CUP µCAP SIZE 40MM A



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NC842T	PLASMAFIT PLUS 3 CUP µCAP SIZE 42MM B
NC844T	PLASMAFIT PLUS 3 CUP µCAP SIZE 44MM C
NC846T	PLASMAFIT PLUS 3 CUP µCAP SIZE 46MM D
NC848T	PLASMAFIT PLUS 3 CUP µCAP SIZE 48MM E
NC850T	PLASMAFIT PLUS 3 CUP µCAP SIZE 50MM F
NC852T	PLASMAFIT PLUS 3 CUP µCAP SIZE 52MM G
NC854T	PLASMAFIT PLUS 3 CUP µCAP SIZE 54MM H
NC856T	PLASMAFIT PLUS 3 CUP µCAP SIZE 56MM I
NC858T	PLASMAFIT PLUS 3 CUP µCAP SIZE 58MM J
NC860T	PLASMAFIT PLUS 3 CUP µCAP SIZE 60MM J
NC862T	PLASMAFIT PLUS 3 CUP µCAP SIZE 62MM J
NC864T	PLASMAFIT PLUS 3 CUP µCAP SIZE 64MM K
NC866T	PLASMAFIT PLUS 3 CUP µCAP SIZE 66MM K
NC868T	PLASMAFIT PLUS 3 CUP µCAP SIZE 68MM K
NC870T	PLASMAFIT PLUS 3 CUP µCAP SIZE 70MM K
NC940T	PLASMAFIT PLUS 5 CUP µCAP SIZE 40MM A
NC942T	PLASMAFIT PLUS 5 CUP µCAP SIZE 42MM B
NC944T	PLASMAFIT PLUS 5 CUP µCAP SIZE 44MM C
NC946T	PLASMAFIT PLUS 7 CUP µCAP SIZE 46MM D
NC948T	PLASMAFIT PLUS 7 CUP µCAP SIZE 48MM E
NC950T	PLASMAFIT PLUS 7 CUP µCAP SIZE 50MM F
NC952T	PLASMAFIT PLUS 7 CUP µCAP SIZE 52MM G
NC954T	PLASMAFIT PLUS 7 CUP µCAP SIZE 54MM H
NC956T	PLASMAFIT PLUS 7 CUP µCAP SIZE 56MM I
NC958T	PLASMAFIT PLUS 7 CUP µCAP SIZE 58MM J
NC960T	PLASMAFIT PLUS 7 CUP µCAP SIZE 60MM J
NC962T	PLASMAFIT PLUS 7 CUP µCAP SIZE 62MM J
NC964T	PLASMAFIT PLUS 7 CUP µCAP SIZE 64MM K
NC966T	PLASMAFIT PLUS 7 CUP µCAP SIZE 66MM K
NC968T	PLASMAFIT PLUS 7 CUP µCAP SIZE 68MM K
NC970T	PLASMAFIT PLUS 7 CUP µCAP SIZE 70MM K

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000168332
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV040T	PLASMAFIT POLY CUP SIZE 40MM B
NV042T	PLASMAFIT POLY CUP SIZE 42MM C
NV044T	PLASMAFIT POLY CUP SIZE 44MM D
NV046T	PLASMAFIT POLY CUP SIZE 46MM E
NV048T	PLASMAFIT POLY CUP SIZE 48MM F
NV050T	PLASMAFIT POLY CUP SIZE 50MM G
NV052T	PLASMAFIT POLY CUP SIZE 52MM H
NV054T	PLASMAFIT POLY CUP SIZE 54MM I
NV056T	PLASMAFIT POLY CUP SIZE 56MM J
NV058T	PLASMAFIT POLY CUP SIZE 58MM K



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NV060T	PLASMAFIT POLY CUP SIZE 60MM L
NV062T	PLASMAFIT POLY CUP SIZE 62MM M
NV140T	PLASMAFIT PLUS CUP SIZE 40MM A
NV142T	PLASMAFIT PLUS CUP SIZE 42MM B
NV144T	PLASMAFIT PLUS CUP SIZE 44MM C
NV146T	PLASMAFIT PLUS CUP SIZE 46MM D
NV148T	PLASMAFIT PLUS CUP SIZE 48MM E
NV150T	PLASMAFIT PLUS CUP SIZE 50MM F
NV152T	PLASMAFIT PLUS CUP SIZE 52MM G
NV154T	PLASMAFIT PLUS CUP SIZE 54MM H
NV156T	PLASMAFIT PLUS CUP SIZE 56MM I
NV158T	PLASMAFIT PLUS CUP SIZE 58MM J
NV160T	PLASMAFIT PLUS CUP SIZE 60MM J
NV162T	PLASMAFIT PLUS CUP SIZE 62MM J
NV164T	PLASMAFIT PLUS CUP SIZE 64MM K
NV166T	PLASMAFIT PLUS CUP SIZE 66MM K
NV168T	PLASMAFIT PLUS CUP SIZE 68MM K
NV170T	PLASMAFIT PLUS CUP SIZE 70MM K
NV240T	PLASMAFIT PLUS 3 CUP SIZE 40MM A
NV242T	PLASMAFIT PLUS 3 CUP SIZE 42MM B
NV244T	PLASMAFIT PLUS 3 CUP SIZE 44MM C
NV246T	PLASMAFIT PLUS 3 CUP SIZE 46MM D
NV248T	PLASMAFIT PLUS 3 CUP SIZE 48MM E
NV250T	PLASMAFIT PLUS 3 CUP SIZE 50MM F
NV252T	PLASMAFIT PLUS 3 CUP SIZE 52MM G
NV254T	PLASMAFIT PLUS 3 CUP SIZE 54MM H
NV256T	PLASMAFIT PLUS 3 CUP SIZE 56MM I
NV258T	PLASMAFIT PLUS 3 CUP SIZE 58MM J
NV260T	PLASMAFIT PLUS 3 CUP SIZE 60MM J
NV262T	PLASMAFIT PLUS 3 CUP SIZE 62MM J
NV264T	PLASMAFIT PLUS 3 CUP SIZE 64MM K
NV266T	PLASMAFIT PLUS 3 CUP SIZE 66MM K
NV268T	PLASMAFIT PLUS 3 CUP SIZE 68MM K
NV270T	PLASMAFIT PLUS 3 CUP SIZE 70MM K
NV340T	PLASMAFIT PLUS 5 CUP SIZE 40MM A
NV342T	PLASMAFIT PLUS 5 CUP SIZE 42MM B
NV344T	PLASMAFIT PLUS 5 CUP SIZE 44MM C
NV346T	PLASMAFIT PLUS 7 CUP SIZE 46MM D
NV348T	PLASMAFIT PLUS 7 CUP SIZE 48MM E
NV350T	PLASMAFIT PLUS 7 CUP SIZE 50MM F
NV352T	PLASMAFIT PLUS 7 CUP SIZE 52MM G
NV354T	PLASMAFIT PLUS 7 CUP SIZE 54MM H
NV356T	PLASMAFIT PLUS 7 CUP SIZE 56MM I
NV358T	PLASMAFIT PLUS 7 CUP SIZE 58MM J
NV360T	PLASMAFIT PLUS 7 CUP SIZE 60MM J
NV362T	PLASMAFIT PLUS 7 CUP SIZE 62MM J
NV364T	PLASMAFIT PLUS 7 CUP SIZE 64MM K



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NV366T	PLASMAFIT PLUS 7 CUP SIZE 66MM K
NV368T	PLASMAFIT PLUS 7 CUP SIZE 68MM K
NV370T	PLASMAFIT PLUS 7 CUP SIZE 70MM K

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000168434
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV201	PE-INSERT E 32MM SYM.
NV202	PE-INSERT F 32MM SYM.
NV203	PE-INSERT G 32MM SYM.
NV204	PE-INSERT H 32MM SYM.
NV205	PE-INSERT I 32MM SYM.
NV206	PE-INSERT J 32MM SYM.
NV207	PE-INSERT K 32MM SYM.
NV208	PE-INSERT L 32MM SYM.
NV209	PE-INSERT M 32MM SYM.
NV289	PE-INSERT C 28MM POST.WALL
NV290	PE-INSERT D 28MM POST.WALL
NV301	PE-INSERT E 32MM POST.WALL
NV302	PE-INSERT F 32MM POST.WALL
NV303	PE-INSERT G 32MM POST.WALL
NV304	PE-INSERT H 32MM POST.WALL
NV305	PE-INSERT I 32MM POST.WALL
NV306	PE-INSERT J 32MM POST.WALL
NV307	PE-INSERT K 32MM POST.WALL
NV308	PE-INSERT L 32MM POST.WALL
NV309	PE-INSERT M 32MM POST.WALL

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000168536
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV182E	VITELENE INSERT A 22.2MM SYM.
NV183E	VITELENE INSERT B 22.2MM SYM.
NV184E	VITELENE INSERT C 22.2MM SYM.
NV189E	VITELENE INSERT C 28MM SYM.
NV190E	VITELENE INSERT D 28MM SYM.
NV191E	VITELENE INSERT E 28MM SYM.
NV192E	VITELENE INSERT F 28MM SYM.
NV193E	VITELENE INSERT G 28MM SYM.
NV194E	VITELENE INSERT H 28MM SYM.
NV195E	VITELENE INSERT I 28MM SYM.
NV201E	VITELENE INSERT E 32MM SYM.
NV202E	VITELENE INSERT F 32MM SYM.



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NV203E	VITELENE INSERT G 32MM SYM.
NV204E	VITELENE INSERT H 32MM SYM.
NV205E	VITELENE INSERT I 32MM SYM.
NV206E	VITELENE INSERT J 32MM SYM.
NV207E	VITELENE INSERT K 32MM SYM.
NV208E	VITELENE INSERT L 32MM SYM.
NV209E	VITELENE INSERT M 32MM SYM.
NV213E	VITELENE INSERT G 36MM SYM.
NV214E	VITELENE INSERT H 36MM SYM.
NV215E	VITELENE INSERT I 36MM SYM.
NV216E	VITELENE INSERT J 36MM SYM.
NV217E	VITELENE INSERT K 36MM SYM.
NV218E	VITELENE INSERT L 36MM SYM.
NV219E	VITELENE INSERT M 36MM SYM.
NV225E	VITELENE INSERT I 40MM SYM.
NV226E	VITELENE INSERT J 40MM SYM.
NV227E	VITELENE INSERT K 40MM SYM.
NV228E	VITELENE INSERT L 40MM SYM.
NV229E	VITELENE INSERT M 40MM SYM.
NV282E	VITELENE INSERT A 22.2MM POST.WALL
NV283E	VITELENE INSERT B 22.2MM POST.WALL
NV284E	VITELENE INSERT C 22.2MM POST.WALL
NV289E	VITELENE INSERT C 28MM POST.WALL
NV290E	VITELENE INSERT D 28MM POST.WALL
NV291E	VITELENE INSERT E 28MM POST.WALL
NV292E	VITELENE INSERT F 28MM POST.WALL
NV293E	VITELENE INSERT G 28MM POST.WALL
NV294E	VITELENE INSERT H 28MM POST.WALL
NV295E	VITELENE INSERT I 28MM POST.WALL
NV301E	VITELENE INSERT E 32MM POST.WALL
NV302E	VITELENE INSERT F 32MM POST.WALL
NV303E	VITELENE INSERT G 32MM POST.WALL
NV304E	VITELENE INSERT H 32MM POST.WALL
NV305E	VITELENE INSERT I 32MM POST.WALL
NV306E	VITELENE INSERT J 32MM POST.WALL
NV307E	VITELENE INSERT K 32MM POST.WALL
NV308E	VITELENE INSERT L 32MM POST.WALL
NV309E	VITELENE INSERT M 32MM POST.WALL
NV313E	VITELENE INSERT G 36MM POST.WALL
NV314E	VITELENE INSERT H 36MM POST.WALL
NV315E	VITELENE INSERT I 36MM POST.WALL
NV316E	VITELENE INSERT J 36MM POST.WALL
NV317E	VITELENE INSERT K 36MM POST.WALL
NV318E	VITELENE INSERT L 36MM POST.WALL
NV319E	VITELENE INSERT M 36MM POST.WALL
NV382E	VITELENE INSERT A 22.2MM 10°ASYM.
NV383E	VITELENE INSERT B 22.2MM 10°ASYM.



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NV384E	VITELENE INSERT C 22.2MM 10°ASYM.
NV389E	VITELENE INSERT C 28MM 10°ASYM.
NV390E	VITELENE INSERT D 28MM 10°ASYM.
NV391E	VITELENE INSERT E 28MM 10°ASYM.
NV401E	VITELENE INSERT E 32MM 10°ASYM.
NV402E	VITELENE INSERT F 32MM 10°ASYM.
NV403E	VITELENE INSERT G 32MM 10°ASYM.
NV404E	VITELENE INSERT H 32MM 10°ASYM.
NV405E	VITELENE INSERT I 32MM 10°ASYM.
NV406E	VITELENE INSERT J 32MM 10°ASYM.
NV407E	VITELENE INSERT K 32MM 10°ASYM.
NV408E	VITELENE INSERT L 32MM 10°ASYM.
NV409E	VITELENE INSERT M 32MM 10°ASYM.

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000168638
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH484T	PLC PRESSFIT-CUP SIZE 44MM
NH486T	PLC PRESSFIT-CUP SIZE 46MM
NH488T	PLC PRESSFIT-CUP SIZE 48MM
NH490T	PLC PRESSFIT-CUP SIZE 50MM
NH492T	PLC PRESSFIT-CUP SIZE 52MM
NH494T	PLC PRESSFIT-CUP SIZE 54MM
NH496T	PLC PRESSFIT-CUP SIZE 56MM
NH498T	PLC PRESSFIT-CUP SIZE 58MM

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016873A
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NK684K	COCR PROSTHESIS HEAD 12/14 28MM S
NK685K	COCR PROSTHESIS HEAD 12/14 28MM M
NK686K	COCR PROSTHESIS HEAD 12/14 28MM L
NK687K	COCR PROSTHESIS HEAD 12/14 28MM XL

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016883C
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH212T	RECONSTRUCTION SHELL 52(48)MM RIGHT
NH222T	RECONSTRUCTION SHELL 52(48)MM LEFT
NH233T	RECONSTRUCTION SHELL 58(54)MM RIGHT
NH243T	RECONSTRUCTION SHELL 58(54)MM LEFT



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NH254T	RECONSTRUCTION SHELL 64(60)MM RIGHT
NH264T	RECONSTRUCTION SHELL 64(60)MM LEFT

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016893E
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NH444T	SCREW CUP SC SIZE 44MM
NH446T	SCREW CUP SC SIZE 46MM
NH448T	SCREW CUP SC SIZE 48MM
NH450T	SCREW CUP SC SIZE 50MM
NH452T	SCREW CUP SC SIZE 52MM
NH454T	SCREW CUP SC SIZE 54MM
NH456T	SCREW CUP SC SIZE 56MM
NH458T	SCREW CUP SC SIZE 58MM
NH460T	SCREW CUP SC SIZE 60MM
NH464T	SCREW CUP SC SIZE 64MM
NH468T	SCREW CUP SC SIZE 68MM

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000016902X
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NK842E	VITELENE LOW PROFILE CUP CEMENT.28/42MM
NK844E	VITELENE LOW PROFILE CUP CEMENT.28/44MM
NK846E	VITELENE LOW PROFILE CUP CEMENT.28/46MM
NK946E	VITELENE LOW PROFILE CUP CEMENT.32/46MM
NK948E	VITELENE LOW PROFILE CUP CEMENT.32/48MM
NK950E	VITELENE LOW PROFILE CUP CEMENT.32/50MM
NK952E	VITELENE LOW PROFILE CUP CEMENT.32/52MM
NK954E	VITELENE LOW PROFILE CUP CEMENT.32/54MM
NK956E	VITELENE LOW PROFILE CUP CEMENT.32/56MM
NK958E	VITELENE LOW PROFILE CUP CEMENT.32/58MM
NK960E	VITELENE LOW PROFILE CUP CEMENT.32/60MM
NK962E	VITELENE LOW PROFILE CUP CEMENT.32/62MM
NK964E	VITELENE LOW PROFILE CUP CEMENT.32/64MM
NK976E	VITELENE LOW PROFILE CUP CEMENT.36/50MM
NK977E	VITELENE LOW PROFILE CUP CEMENT.36/52MM
NK978E	VITELENE LOW PROFILE CUP CEMENT.36/54MM
NK979E	VITELENE LOW PROFILE CUP CEMENT.36/56MM
NK980E	VITELENE LOW PROFILE CUP CEMENT.36/58MM
NK981E	VITELENE LOW PROFILE CUP CEMENT.36/60MM
NK982E	VITELENE LOW PROFILE CUP CEMENT.36/62MM
NK983E	VITELENE LOW PROFILE CUP CEMENT.36/64MM



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000025352R
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV413E	VITELENE INSERT G 36MM 10°ASYM.
NV414E	VITELENE INSERT H 36MM 10°ASYM.
NV415E	VITELENE INSERT I 36MM 10°ASYM.
NV416E	VITELENE INSERT J 36MM 10°ASYM.
NV417E	VITELENE INSERT K 36MM 10°ASYM.
NV489E	VITELENE INSERT C 28MM 20°ASYM.REV
NV490E	VITELENE INSERT D 28MM 20°ASYM.REV
NV491E	VITELENE INSERT E 28MM 20°ASYM.REV
NV501E	VITELENE INSERT E 32MM 20°ASYM.REV
NV502E	VITELENE INSERT F 32MM 20°ASYM.REV
NV503E	VITELENE INSERT G 32MM 20°ASYM.REV
NV504E	VITELENE INSERT H 32MM 20°ASYM.REV
NV505E	VITELENE INSERT I 32MM 20°ASYM.REV
NV506E	VITELENE INSERT J 32MM 20°ASYM.REV
NV507E	VITELENE INSERT K 32MM 20°ASYM.REV
NV513E	VITELENE INSERT G 36MM 20°ASYM.REV
NV514E	VITELENE INSERT H 36MM 20°ASYM.REV
NV515E	VITELENE INSERT I 36MM 20°ASYM.REV
NV516E	VITELENE INSERT J 36MM 20°ASYM.REV
NV517E	VITELENE INSERT K 36MM 20°ASYM.REV
NV589E	VITELENE INSERT C 28MM SYM.+4MM REV
NV590E	VITELENE INSERT D 28MM SYM.+4MM REV
NV591E	VITELENE INSERT E 28MM SYM.+4MM REV
NV601E	VITELENE INSERT E 32MM SYM.+4MM REV
NV602E	VITELENE INSERT F 32MM SYM.+4MM REV
NV603E	VITELENE INSERT G 32MM SYM.+4MM REV
NV604E	VITELENE INSERT H 32MM SYM.+4MM REV
NV605E	VITELENE INSERT I 32MM SYM.+4MM REV
NV606E	VITELENE INSERT J 32MM SYM.+4MM REV
NV607E	VITELENE INSERT K 32MM SYM.+4MM REV
NV613E	VITELENE INSERT G 36MM SYM.+4MM REV
NV614E	VITELENE INSERT H 36MM SYM.+4MM REV
NV615E	VITELENE INSERT I 36MM SYM.+4MM REV
NV616E	VITELENE INSERT J 36MM SYM.+4MM REV
NV617E	VITELENE INSERT K 36MM SYM.+4MM REV



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

Class	III
Category	MDN 1102
Basic UDI-DI	40392390000025362T
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV944T	PLASMAFIT REVISION STRUCTAN SIZE 44MM C
NV946T	PLASMAFIT REVISION STRUCTAN SIZE 46MM D
NV948T	PLASMAFIT REVISION STRUCTAN SIZE 48MM E
NV950T	PLASMAFIT REVISION STRUCTAN SIZE 50MM F
NV952T	PLASMAFIT REVISION STRUCTAN SIZE 52MM G
NV954T	PLASMAFIT REVISION STRUCTAN SIZE 54MM H
NV956T	PLASMAFIT REVISION STRUCTAN SIZE 56MM I
NV958T	PLASMAFIT REVISION STRUCTAN SIZE 58MM J
NV960T	PLASMAFIT REVISION STRUCTAN SIZE 60MM J
NV962T	PLASMAFIT REVISION STRUCTAN SIZE 62MM J
NV964T	PLASMAFIT REVISION STRUCTAN SIZE 64MM K
NV966T	PLASMAFIT REVISION STRUCTAN SIZE 66MM K
NV968T	PLASMAFIT REVISION STRUCTAN SIZE 68MM K
NV970T	PLASMAFIT REVISION STRUCTAN SIZE 70MM K
NV972T	PLASMAFIT REVISION STRUCTAN SIZE 72MM K

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000274434
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NJ180K	DUAL MOB.PROSTHESIS HEAD 8/10 22.2MM S
NJ181K	DUAL MOB.PROSTHESIS HEAD 8/10 22.2MM M
NJ182K	DUAL MOB.PROSTHESIS HEAD 8/10 22.2MM L
NJ190K	DUAL MOB.PROSTHESIS HEAD 8/10 28MM S
NJ191K	DUAL MOB.PROSTHESIS HEAD 8/10 28MM M
NJ192K	DUAL MOB.PROSTHESIS HEAD 8/10 28MM L
NK1090K	DUAL MOB.PROSTHESIS HEAD 12/14 28MM S
NK1091K	DUAL MOB.PROSTHESIS HEAD 12/14 28MM M
NK1092K	DUAL MOB.PROSTHESIS HEAD 12/14 28MM L

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000274536
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV1010Z	DUAL MOBILITY INSERT D
NV1011Z	DUAL MOBILITY INSERT E
NV1012Z	DUAL MOBILITY INSERT F
NV1013Z	DUAL MOBILITY INSERT G
NV1014Z	DUAL MOBILITY INSERT H



DNV

Certificate no.: 20004GB450240516
Place and date: Hamburg, 2024-05-16

NV1015Z	DUAL MOBILITY INSERT I
NV1016Z	DUAL MOBILITY INSERT J
NV1017Z	DUAL MOBILITY INSERT K

Class	III
Category	MDN 1102
Basic UDI-DI	403923900000274638
Intended purpose	The implant is used as a component of a human hip endoprosthesis.
Model (REF#)	Medical device name
NV1030E	VITELENE DUAL MOBILITY HEAD D 22.2MM
NV1031E	VITELENE DUAL MOBILITY HEAD E 22.2MM
NV1032E	VITELENE DUAL MOBILITY HEAD F 22.2MM
NV1043E	VITELENE DUAL MOBILITY HEAD G 28MM
NV1044E	VITELENE DUAL MOBILITY HEAD H 28MM
NV1045E	VITELENE DUAL MOBILITY HEAD I 28MM
NV1046E	VITELENE DUAL MOBILITY HEAD J 28MM
NV1047E	VITELENE DUAL MOBILITY HEAD K 28MM

