

Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road

New Delhi-110002

Phone No-011-23236965

Fax: 23236973

Dated : 05-JUL-2022

File No. : AZ/MD/2022/000003

M/s ORTHOFLEX MEDISYS INDIA PVT

LTD,

REG OFFICE 2ND FLOOR SHIV

MARKET OPP BUS STATION

VISNAGAR

VISNAGAR, --, Gujarat (India) - 384315

Telephone No.: 09727973005 FAX:

02765225295 Email: rakemax@yahoo.com

**Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in
Sir, Form MD-9 under Medical Device Rules, 2017- regarding.**

Manufacturing licence No. MFG/MD/2021/000156 in Form MD-9 is hereby forwarded to you.

This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

Yours faithfully

VENUGOPAL G SOMANI
Licence
Stamp
Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
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CONTROL AUTHORITY (INDIA),
serialNumber=2522118a1c0bba41522525ff
ca0705074b4997e6b2f4b5c8d81cf282adeaf
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FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2021/000156

Endorsement No. 1

1. M/s ORTHOFLEX MEDISYS INDIA PVT LTD, REG OFFICE 2ND FLOOR SHIV MARKET OPP BUS STATION VISNAGARVISNAGAR, --, Gujarat (India) - 384315 Telephone No.: 09727973005 FAX: 02765225295 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Orthoflex Medisys India Pvt Ltd, survey no 1591, shed no 7, ramdevchikori industrialestate, vijapur road, at visnagar, dist mehsana gujrat 284315 india, Mehsana, Gujarat (India) - 384315 Telephone No.: 9727973005 FAX: 2765 225295

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
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pseudonym=112046a34e21727bacb25574
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serialNumber=e97f241aa0c0bba41522525f
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1	<p>Generic Name:Total Hip Replacement {SS316L}</p> <p>Model No.:Austin Moore Prosthesis - 35mm To 55mm (Diff 1mm/ 2.0mm) ,Thompson Prosthesis - 35mm To 55mm (Diff 1mm/ 2.0mm) ,Femoral Stem Collarless (1 25/ 130 / 135/ 140 Degree) (Un-Cemented)) Total Hip Replacement - 6.0 mm To 20.0mm (Diff 1.0 mm / 2.0 mm) ,Femoral Stem -Collared (125/ 130/ 135/ 140 Degree) (Un Cemented) Total Hip Replacement - 6.0 mm To 20.0mm (Diff 1.0 mm / 2.0mm) ,Femoral Stem- Collarless (125/ 130/ 135/ 140 Degree) (Cemented) (Total Hip Replacement) - 6.0mm to 15.0mm ,Femoral Stem Collared (125/ 130/ 135/ 140 Degree) (Cemented) (Total Hip Replacement) - 6.0mm to 15.0mm ,Femoral Revision Stem Calcar (Stralgh/Bowed) (125/ 130/ 135/ 140 Degree) (cemented/Un Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff• 1.0mm/ 1.5mm/ 2.0mm/ 2.5mm) Length- 200 mm to 400 mm) (Diff 25mm) ,Bipolar Hip Prosthesis - 35 mm To 55 mm (Diff 1mm/2.0mm) ,Femoral Revision Stem (With Platform) (Stralgh/Bowed) (125/ 130/ 135/ 140 Degree) Left / Right) (Un Cemented) Total Hip Replacement - 2.0 mm to 16.5 mm (Diff- 1.5 mm) Length- 200 mm to 400 mm) (Diff 25mm) ,Femoral Revision Stem -Collarless (125/ 130/ 135/ 140 Degree)(Nexus) - (Cemented) -Total Hip Replacement - 200 mm lo 300 mm (Diff 50mm) ,Femoral Revision Stem Collared (125/ 130/ 135/ 140 Degree) (Left / Right) (Cemented) Total Hip Replacement - 200 mm lo 300 mm (Diff 50mm ,Modular Biopolar Cup - 35 mm Lo 55 mm (Diff• 1.0mm) ,Femoral Calcar Revision Stem (125/ 130/ 135/ 140 Degree) (Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff- 1.0mm/ 1.5mm/2.0mm/ 2.5mm) Height 8.0 to 15.0 inch (Diff 1.0/0.5 inch) ,Internal Head Total Hip Replacement - 22.0mm to 48.0mm mm (Diff• 1 mm/2.0mm) 1.0mm to 20.0mm (Diff 0.5mmf 1 mm 2.0mmf 3.0mm/ 5.0 mm) ,Acetabular Cup (Un -Cemented) Total Hip Replacement - 35 mm to 75 mm (Diff - 1 mm/ 2.0mm) ,Screw for Acetabular Cup (Un -Cemented) Total Hip Replacement - 10mm to 64mm (Diff 2.0mm) ,Dual Mobility Acetabular Cup (Un Cemented) Total Hip Replacement - 35 mm to 75 mm (Diff• 1 mm/ 2.0mm) ,Dual Mobility Acetabular Cup - (Cemented) Total Hip Replacement - 35 mm to 75 mm (Diff• 1 mm/ 2.0mm) ,Modular Self Centering Cup - 26 mm (37 mm Lo 43 mm)/ 28 mm (45 mm to 57 mm) (Diff 2.0mm)</p> <p>Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.</p> <p>Class of medical device:Class D</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS</p>
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 Date: 2022.07.05 16:19:47 +05'30'

2

Generic Name:Total Hip Replacement {Titanium}

Model No.:Internal Head Total HIP Replacement - 22.0mm to 48.0mm mm (Diff 1 mm/ 2.0mm) 1.0mm to 20.0mm (Diff. 0.5mm/ 1mm/ 2.0mm/ 3.0mm/ 5.0mm) ,Austin Moore Prosthesis - 35 mm To 55mm (Diff 1mm/ 2.0mm) ,Thompson Prosthesis - 35 mm To 55mm (Diff 1mm/ 2.0mm) ,Bipolar Prosthesis - 35 mm To 55mm (Diff 1mm/ 2.0mm) ,Femoral Stem-Collarless (125/ 130/ 135/ 140 Degree) (Un-Cemented)) Total Hip Replacement - 6.0mm to 20.0 mm (Diff 1.0mm/ 2.0mm) ,Femoral Stem Collared (125/ 130/ 135/ 140Degree) (Un -Cemented) Total Hip Replacement - 6.0mm to 20.0mm (Diff-1.0 mm/ 2.0mm) ,Femoral Stem (Cemented) (Total Hip Replacement) - 6.0 mm to 15.0 mm ,Femoral Revision Stem Calcar (Straight/Bowed)(125/ 130/ 135/ 140 Degree) (Un-Cemented) Total Hip Replacement - 8.0mm to 25 ,Femoral Revision Stem (With Platform) (Straight/Bowed) (125/ 130/ 135/ 140 Degree) Left/ Right) (Un Cemented) Total Hip Replacement - 12.0 mm to 16.5 mm (Diff• 11.5 mm) ,Femoral Revision Stem Collarless (125/ 130/ 135/140 Degree)(Nexus) (Cemented)Total Hip Replacement - 200 mm to 300 mm (Diff 50mm) ,Femoral Revision Stem Collared f125/ 130/ 135/ 140 Degree) Left/ Right) (Cemented) Total Hip Replacement - 200 mm to 300 mm (Diff 50mm) ,Femoral Calcar Revision Stem (125/ 130/ 135/140 Degree) (Cemented) Total Hip Replacement - 8.0 mm to 25.0 mm (Diff 1.0mm/ 1.5mm/ 2.0 mm/ 2.5mm Height-8.0 to 15.0 inch (Diff-1.0/0.5 inch) ,Acetabular Cup (Un -Cemented) Total HIP Replacement - 35mm to 75mm (Diff 1mm/ 2.0 mm) ,Screw for Acetabular Cup (Un -Cemented) - Total Hip Replacement - 10mm to 64mm (Diff 2.0mm) ,Dual Mobility Acelabular Cup (Un-Cemented) Total Hip Replacement - 35mm to 75mm (Diff 1mm/ 2.0mm) ,Dual Mobility Acetabular Cup (Cemented) - Total Hip Replacement - 35mm to 75mm Diff 1mm/ 2.0mm) ,Modular Self Centering Cup - 26mm (37mm to 43mm) 28mm (45mm to 57mm (Diff 2.0mm) ,Modular Bipolar Cup - 35mm to 55mm (Diff 1.0mm)

Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.

Class of medical device:Class D

Material of construction:Titanium

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS

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3

Generic Name:Total Hip Replacement {CoCr}

Model No.:Femoral Stem- Collarless (125/ 130/ 135/ 140 Degree)- (Cemented) (Total Hip Replacement) - 8.0mm to 25.0 mm (Diff-1.0mm/ 1.5mm/ 2.0mm/ 2.5mm) Height-8.0 to 15.0 inch (Diff- 1.0/0.5 inch) ,Femoral Revision Stem Collared (Straight/Bowed) (125/ 130/ 135/140 Degree) (Un-Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff 1.0mm/ 1.5mm/ 2.0 mml 2.5 mm) length-200 mm to 400 mm) (Diff. 25mm) ,Femoral Revision Stem -Collarless (125/ 130/ 135/ 140 Degree) -(Cemented) - Total Hip Replacement - 200 mm to 300 mm (Diff. 50mm) ,Femoral Revision Stem Collared (125/ 130/ 135/ 140 Degree) Left / Right) (Cemented) Total Hip Replacement - 200 mm to 300 mm (Diff- 50mm) ,Femoral Calcar Revision Stem (125/ 130/135/140 Degree) (Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff-1.0mm 1.5mm/ 2.0mml 2.5mm) Height• 8.0 to 15.0 inch (Diff-1.0/0.5 Inch) , Internal Head - Total Hip Replacement - 22.0mm to 48.0mm mm (Diff• 1 mm/ 2.0mm) 1.0mm to 20.0mm (Diff• 0.5mm 1 mm/ 2.0mm/ 3.0 mm/5.0mm) ,Femoral Stem Collarless (125/ 130/ 135/ 140 Degree) (Un Cemented)- Total Hip Replacement - 6.0mm to 20.0mm (Diff- 1.0mm/ 2.0mm) ,Femoral Revision Stem (With Platform) (Straight/Bowed) (125/ 130/ 135/ 140 Degree)- Left/ Right (Un-Cemented)- Total Hip Replacement - 12.0mm to 16.5mm (Diff. 1.5 mm) Length- 200mm to 400mm (Ditt- 25mm)

Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.

Class of medical device:Class D

Material of construction:CoCr

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHO FLEX MEDISYS

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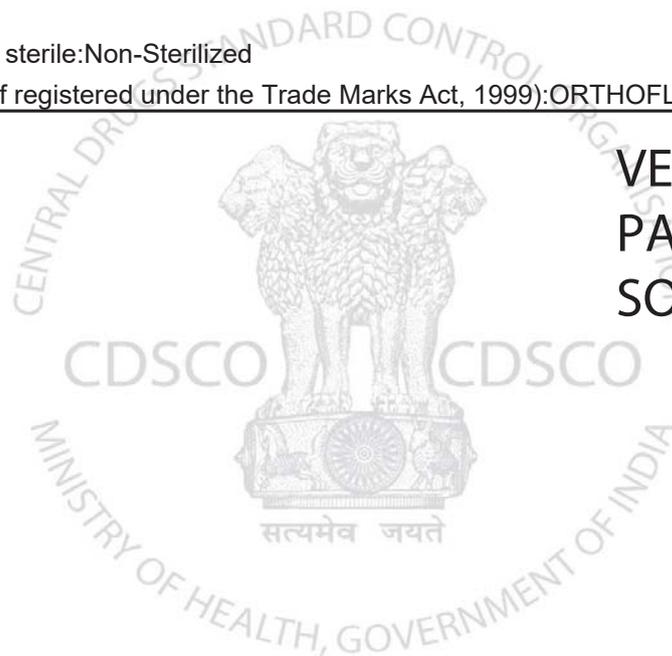
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4	<p>Generic Name:Total Hip Replacement {UHMWPE}</p> <p>Model No.:Bipolar Prosthesis - 35mm to 55mm (Diff 1mm/ 2.0mm) ,Acetabular Cup T1 (Cemented) Total Hip Replacement - 35mm to 66mm (Diff 1mm/ 2.0mm) ,Acetabular Cup T2 Cemented) Total Hip Replacement - 35mm to 66mm (Diff 1mm/ 2.0mm) ,Acetabular Cup 10/20 Degree Lift (Cemented)- Total Hip Replacement - 35mm to 66mm (Diff 1mm/ 2.0mm) , Dual Mobility Liner (+4Neutral / 10/ 20 Degree Lift) (Un -Cemented) Total Hip Replacement - 35mm to 75mm (Diff 1mm/ 2.0mm) ,Cement Restrictor - 38.0mm ,Modular Self Centering Cup - 26 MM (37 mm to 43 mm) 28 MM (45 mm to 57 mm) (Diff 2.0mm) ,Modular Bipolar Cup - 35 mm to 55 mm (Diff 1.0mm)</p> <p>Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.</p> <p>Class of medical device:Class D</p> <p>Material of construction:UHMWPE</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHO FLEX MEDISYS</p>
5	<p>Generic Name:Total Hip Replacement {Ceramic-ISO 6474}</p> <p>Model No.:Internal Head- Total Hip Replacement - 22.0mm to 48.0mm</p> <p>Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.</p> <p>Class of medical device:Class D</p> <p>Material of construction:Ceramic-ISO 6474</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHO FLEX MEDISYS</p>

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 Date: 2022.07.05 16:20:13 +05'30'

6	<p>Generic Name:Total Hip Replacement {PMMA}</p> <p>Model No.:Centralizer - 8mm/ 10mm/ 12mm/ 14mm</p> <p>Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.</p> <p>Class of medical device:Class D</p> <p>Material of construction:PMMA</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS</p>
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 Date: 2022.07.05 16:20:21 +05'30'

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Generic Name:Total Hip Replacement {SS(ISO 5832-1)}

Model No.:Bipolar Prosthesis - 35mm To 55mm (Diff 1mm. 2.0mm) ,Austin Moore Prosthesis - 35mm To 55mm (Diff 1mm. 2.0mm) ,Thompson Prosthesis - 35mm To 55mm (Diff 1mm. 2.0 mm) ,Femoral Stem Collarless (1 25/ 130 / 135/ 140 Degree) (Un-Cemented)) Total Hip Replacement - 6.0 mm/ 10mm/ 20.0mm (Diff 1.0mm/ 2.0mm ,Internal Head Total Hip Replacement - 22.0mm to 48.0mm (Diff 1 mm/ 2.0mm) 1.0mm to 20.0mm (Diff- 0.5mm/ 1 mm/ 2.0mm/ 3.0mm/ 5.0mm) ,Acetabular Cup (Un -Cemented) Total Hip Replacement - 35 mm 10 75 mm (Diff- 1mm/ 2.0mm) ,Screw for Acetabular Cup (Un -Cemented) - Total Hip Replacement - 10 mm to 64 mm (Diff- 2.0mm) ,Dual Mobility Acetabular Cup - (Un-Cemented)- Total Hip Replacement - 35 mm to 75 mm (Diff- 1mm/ 2.0mm) ,Dual Mobility Acetabular Cup - (Cemented) - Total Hip Replacement - 35 mm to 75 mm (Diff.1 mm/ 2.0mm) ,Modular Self Centering Cup - 26 MM (37 mm to 43 mm) 28 MM (45 mm to 57 mm)(Diff• 2.0mm) Modular Biopolar Cup - 35 mm to 57 mm (Diff 1.0mm) ,Femoral Stem Collared (125/ 130/ 135/ 140 Degree) (Un Cemented) Total Hip Replacement - 6.0mm to 20.0mm (Diff. 1.0 mm/2.0mm) , Femoral Stem (Cemented) (Total Hip Replacement) - 6.0 mm to 15.0 mm ,Femoral Revision Stem Calcar (Straight/Bowed) (125/ 130/ 135/ 140 Degree) (Un- Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff 1.0mm/ 1.5mm/ 2.0mm/ 2.5mm) Helghl-200 mm to 400 mm) (Diff 25 mm) ,Femoral Revision Stem (With Platform) (Straight/Bowed) (125/ 130/ 135/ 140 Degree)- Left/ Right) (Un Cemented) Total Hip Replacement - 12.0 mm to 16.5 mm (Diff 1.5 mm) ,Femoral Revision Stem -Collarless (125/ 130/135/ 140 Degree)(NEXUS) (Cemented) Total Hip Replacement - 200 mm to 300 mm (Diff 50mm) ,Femoral Revision Stem Collared (125/ 130/ 135/ 140 Degree)- Left / Right) (Cemented) Total HIP Replacement - 200 mm to 300 mm (Diff 50mm) ,Femoral Calcar Revision Stem (125/ 130/ 135/140 Degree) (Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff 1.0mm/ 1.5mm/ 2.0mm/ 2.5mm) Height 8.0 to 15.0 Inch (Diff 1.0/ 0.5 inch)

Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.

Class of medical device:Class D

Material of construction:SS(ISO 58321)

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS

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cn=VENUGOPAL G SOMANI
Date: 2022.07.05 16:20:44 +05'30'

8

Generic Name:Total Hip Replacement {XLPE}

Model No.:Acetabular Cup 1 of 20 Degree Lift (Cemented) Total HIP Replacement - 35mm to 66mm (Diff 1mm/ 2.0mm) ,Bipolar Prosthesis - 35mm to 55mm (Diff 1mm/ 2.0mm) ,Acetabular Cup T1 (Cemented) Total Hip Replacement - 35mm to 66mm (Diff 1mm/ 2.0mm) ,Acetabular Cup T2 Cemented) Total Hip Replacement - 35mm to 66mm (Diff 1mm/ 2.0mm) ,Dual Mobility liner (+4Neutral / 10/ 20 Degree Lift) (Un -Cemented) Total Hip Replacement - 35 mm to 75 mm (Diff 1.0mm/ 2.0mm) ,Cement Restrictor - 38.0mm ,Modular Self Centering Cup - 26 MM (37 mm to 43 mm) 28 MM (45 mm to 57 mm) (Diff 2.0mm) ,Modular Bipolar Cup - 35 mm to 57 mm (Diff 1.0mm)

Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.

Class of medical device:Class D

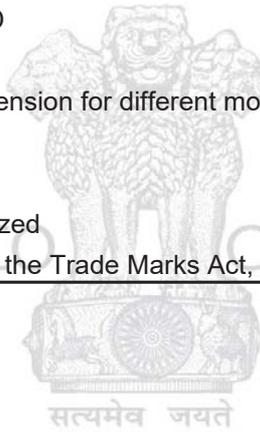
Material of construction:XLPE

Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):ORTHO FLEX MEDISYS



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AL G
SOMANI**

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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e971241aa0c0bba1522525f6a0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
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9	<p>Generic Name:Total Hip Replacement {SS(ISO 5832-9)}</p> <p>Model No.:Femoral Revision Stem Collarless (125/ 130/ 135/ 140 Degree)(NEXUS) (Cemented) Total Hip Replacement - 200mm to 300mm (Diff 50mm) ,Austin Moore Prosthesis - 35mm to 55mm (Diff 1mm/ 2.0mm) ,Femoral Stem Collarless (125/ 130/ 135/ 140 Degree) (Un-Cemented) Total Hip Replacement - 6.0mm to 20.0mm (Diff• 1.0 mm/ 2.0mm) ,Femoral Stem Collared (125/ 130/ 135/ 140 Degree) (Un Cemented) Total Hip Replacement - 6.0mm to 20.0mm (Diff 1.0 mm/ 2.0mm) ,Femoral Revision Stem Calcar (Straight/Bowed) (125/ 130/ 135/ 140 Degree) (Un Cemented) Total HIP Replacement - 8.0mm to 25.0 mm (Diff 1.0mm/ 1.5 mm/ 2.0mm/ 2.5mm) Heighl-200 mm to 400 mm) (Diff- 25 mm) ,Femoral Revision Stem (With Platform) (Straight/Bowed) (125/ 130/ 135/ 140 Degree)-Left/ Right) (Un Cemented) Total Hip Replacement - 12.0 mm to 16.5 mm (Diff 1.5mm) ,Modular Biopolar Cup - 35 mm to 55 mm (Diff 1.0mm) ,Thompson Prosthesis - 35mm to 55mm (Diff 1mm/ 2.0mm) ,Bipolar Prosthesis - 35mm to 55mm (Diff 1mm/ 2.0mm) ,Femoral Stem (Cemented) (Total Hip Replacement) - 6.0 mm to 15.0 mm ,Acetabular Cup (Un Cemented) Total HIP Replacement 3 - 5 mm to75 mm (Diff 1mm/ 2.0mm) ,Femoral Revision Stem Collared (125/ 130/ 135/ 140 Degree) Left/ Right) (Cemented) Total Hip Replacement - 200 mm to 300 mm (Diff 50mm) ,Femoral Calcar Revision Stem (125/ 130/135/ 140 Degree) (Cemented) Total Hip Replacement - 8.0mm to 25.0 mm (Diff 1.0mm/ 1.5mm/ 2.0mm/ 2.5mm) Heighl-200 mm to 400 mm) (Diff- 25 mm) , Internal Head Total Hip Replacement - 22.0mm to 48.0mm mm (Diff 1 mm/ 2.0mm) 1.0mm to 20.0mm (Diff• 0.5mm/ 1 mm/ 2.0mm/ 3.0 mmf5.0mm) ,Screw for Acetabular Cup (Un - cemented) Total Hip Replacement - 10 mm to 64 mm (Diff 2.0mm) ,Dual Mobility Acetabular Cup (Un-Cemented) Total Hip Replacement - 35 mm to 75 mm (Diff 1mm/ 2.0mm) ,Dual Mobility Acetabular Cup (Cemented) Total Hip Replacement - 35 mm to 75 mm (Diff 1mm/ 2.0 mm) ,Modular Self Centering Cup - 26 MM (37 mm to 43 mm) 28 MM (45 mm to 57 mm) (Diff 2.0mm)</p> <p>Intended Use:Total Hip Replacement (Un-Cemented) is intended for use in the total hip arthroplasty and is intended for pressfit (Cementless) use. Total hip arthroplasty is intended to provide increase patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to sit and support the components. Total hip replacement is indicated in the following conditions.(a) Correction of function deformity. (b) Non inflammatory degenerative joint disease (changes) including osteoarthritis, traumatic/Rheumatoid arthritis, congenital hip dysplasia and avascular necrosis. (c) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement unmanaged by other procedures. (d) revision procedure when other devices are failed.</p> <p>Class of medical device:Class D</p> <p>Material of construction:SS(ISO 58329)</p> <p>Dimension(if any):Different Dimension for different model, dimension with model as mentioned below.</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):ORTHOFLEX MEDISYS</p>
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Place:

Date05-Jul-22

VENUGOPAL G SOMANI
Central Licensing Authority
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Date: 2022.07.05 16:21:06 +05'30'