



EC Design Examination Certificate

Certificate No.:
11251-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-208081-2010-PRC-IND

Valid Until:
27 February 2022

This is to certify that:

Total Knee Replacement prosthesis (Brand :Altius™, Model: Buechel – Pappas High Flex Total Knee Replacement System).

Manufactured by:

TTK Healthcare Limited (Ortho Division)
290, Sidco Industrial Estate, Ambattur 600 098, Chennai, India

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 (Module B1) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 30 October 2017



For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB 0434) EC Design Examination Certificate Approval no. 9620-2017-CE-IND-NA following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-10-30

Products covered by this Certificate:

Type of medical device and identification no.: Total Knee Replacement prosthesis (Brand :Altius™, Model: Buechel – Pappas High Flex Total Knee Replacement System).	Medical Device Class: III	GMDN code: 46585
Short description of the Medical Device: Total Knee Replacement Prosthesis is intended to provide primary or revision options to the surgeons to reduce or eliminate pain, restore motion, and/or correct deformity. The Buechel-Pappas High Flex Total Knee Replacement System consists of the following: a femoral and a tibial component made of Cobalt-Chromium (Co- Cr) alloy, mobile bearing / partially conforming bearing and an all poly patellar component made of UHMWPE. Method of sterilization is ethylene oxide.		
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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate