



EU Quality Management Certificate



This is to certify that the company

IBEX Innovations Ltd

NETPark, Explorer 2
TS21 3FF
Sedgefield
United Kingdom

SRN: GB-MF-000029350

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	549655 MDR2017Q
Certificate ID	1000165192
Effective date	2024-02-22
Expiry date	2029-01-31
Frankfurt am Main,	2024-02-22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)





Annex to EU Quality Management Certificate
SRN of Manufacturer: GB-MF-000029350
Certificate ID: 1000165192

EU Representative

Advena Limited
Tower Street
BKR 4013 Swatar
Malta

SRN: MT-AR-000000234

Device categories and variants covered by this certificate:

Device category: **MDA 0315 Software**
Product name: IBEX Bone Health product (IBEX BH)
Risk classification: IIa
Basic-UDI-DI: 506096875TVBHPL6
Intended purpose: The purpose of IBEX BH is to return a measure of aBMD and T-score from a standard DR of the forearm/wrist within automatically selected regions of interest (ROIs) at the Ultra Distal Radius and the 1/3 Distal Radius examination sites.
IBEX BH returns the same outputs of aBMD and T-Score at the examination site as those returned by dual-energy x-ray absorptiometry (DXA), the current WHO standard for diagnosis of osteoporosis. These outputs may be used by a qualified healthcare professional to support a decision on the diagnosis, referral treatment or therapy of bone health.

Examinations and tests performed:

549655_A212120MED_01 dated 2023-12-01
549655_A212120MED_01 IBEX BH dated 2023-11-22

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a