

EC DECLARATION OF CONFORMITY

We, MedXPress.Pro, Slachthuislaan 1, box 102, 3000 Leuven, Belgium

hereby declare under our sole responsibility that the CE marked product(s) to which this declaration relates,

EZCOVER® Probe Covers family including Gel-Vision, Gel Free versions

See Annex I for different models

that have been classified as Class I Sterile medical devices, according to Annex IX, rule I,

and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices, as amended by Directive 2007/47/EC,

and are in conformity with the relevant standards:

EN ISO14971: 2012, EN ISO10993-1:2009, EN ISO10993-5:2009, EN ISO10993-7:2008, EN ISO10993-10:2010, EN ISO11607-1:2019, EN ISO11607-2:2019, EN556-1:2001, EN ISO11135-1:2014, EN ISO11737-1:2018, EN ISO11737-2:2019, EN ISO15223-1:2016, EN1041:2008, IEC62366-1:2015,

and guided by:

Meddev 2.1/1(Rev 1) April 1994, Meddev 2.1/1(Rev 9) June 2010, Meddev 2.7/1 (Rev 4) June 2016, Meddev 2.12/2 (Rev 2) Jan 2021, Meddev 2.5/5 (Rev 3) Feb 1998, Meddev 2.5/5 (Rev 3) June 1998 and Meddev 2.12/1 (Rev 8) Jan 2013

and are subject to the procedure set out in Annex V of the Council Directive 93/42/EEC, as amended by Directive 2007/47/EC.

Note: the sterile ultrasound gel which is part of the packaging is CE-marked by NB 1639, SGS Belgium.

This declaration is made on base of the quality assurance certificate N°. PGH-2017-021, delivered by Notified Body n° 1282, Ente Certificazione Macchine srl. on: 09/11/2018.

This certificate is valid for devices released from the following site (s) : Slachthuislaan 1, box 102, 3000 Leuven, Belgium

Signature :



Date : 23/05/2021

Name : Dr Admir Hadzic

Function : CEO MedXPress.Pro

Effective

Annex I – Product models:

EZCOVER®

Medical Device Name	Product Code	Size (W x L cm)
EZCOVER® Gel-Vision 30cm long	PCG15030	15 x 30
EZCOVER® Gel-Vision 60cm long	PCG15061	15 x 61
EZCOVER® Gel-Vision 122cm long	PCG15122	15 x 122
EZCOVER® Gel-Vision 244cm long	PCG15244	15 x 244
EZCOVER® Gel-Free 30cm long	PCAG15030	15 x 30
EZCOVER® Gel-Free 61cm long	PCAG15061	15 x 61
EZCOVER® Gel-Free 122cm long	PCAG15122	15 x 122
EZCOVER® Gel-Free 244cm long	PCAG15244	15 x 244

EZCOVER® STOP

Medical Device Name	Product Code	Size (W x L cm)
EZCOVER® STOP Gel-Vision 30cm long	PCT15030	15 x 30
EZCOVER® STOP Gel-Vision 61cm long	PCT15061	15 x 61
EZCOVER® STOP Gel-Vision 122cm long	PCT15122	15 x 122
EZCOVER® STOP Gel-Vision 244cm long	PCT15244	15 x 244
EZCOVER® STOP Gel-Free 30cm long	PCAT15030	15 x 30
EZCOVER® STOP Gel-Free 61cm long	PCAT15061	15 x 61
EZCOVER® STOP Gel-Free 122cm long	PCAT15122	15 x 122
EZCOVER® STOP Gel-Free 244cm long	PCAT15244	15 x 244