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DECLARATION OF CONFORMITY

Manufacturer	hearX SA (Pty) Ltd
Manufacturer address	hearX SA 180 Garsfontein Road Ashley Gardens Office Park, Building 2 Pretoria, South Africa
EC Rep address	Variphone International Deusterstraat 72, 3990 Peer, Belgium
Product	hearScope Digital video otoscope Medical device class I, Rule 10 GMDN code 12849 (Outer ear otoscope)

The product(s) described above are in conformity with Annex VII of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The harmonised standards that are applied in full or in part in order to meet the essential requirements are

EN 60601-1-2:2015

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 62304:2006/AC:2008

EN ISO 10993-1:2009/AC:2010

EN 1041:2008/A1:2013

Nic Klopper
Chief Executive Officer (CEO)

7 October 2019

Date