

### **PRESS RELEASE**

# REGULATED INFORMATION INSIDE INFORMATION

## MDxHealth Receives ISO 13485:2016 Certification for Dutch Laboratory

- Key step for MDxHealth's in vitro diagnostic (IVD) strategy in Europe
- Certification enables development, manufacturing and distribution of IVD products

**IRVINE, CA, and HERSTAL, BELGIUM, December 16, 2016** – MDxHealth SA (Euronext: MDXH), announces that its laboratory in Nijmegen, The Netherlands has received ISO 13485:2016 certification for the design, development, manufacture and distribution of in vitro molecular diagnostic products, as well as client services and service testing for molecular diagnostic detection of oncological diseases.

ISO 13485:2016 is the established quality standard for manufacturers of finished medical devices and/or critical components within a medical device platform. The standard specifies requirements for a quality management system to demonstrate a company's ability to consistently provide products that meet applicable statutory and regulatory requirements.

"ISO certification of our Dutch operation is an important milestone and a key step for our in vitro diagnostics strategy for Europe and other international markets," **reported Dr. Jan Groen, Chief Executive Officer of MDxHealth.** "Under this certification we can develop, manufacture and distribute in vitro diagnostic (IVD) products, and now we can begin global marketing and distribution of our SelectMDx IVD kit over the course of the coming year."

## **About MDxHealth**

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. information, visit mdxhealth.com For more and follow us on Twitter twitter.com/mdxhealth.

#### For more information:

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This press release contains forward-looking statements and estimates with respect to the anticipated future performance of MDxHealth and the market in which it operates. Such statements and estimates are based on

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