MEDEC

CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

MEDEC Applauds the Government of Canada's Commitment to Regulate Commercially Reprocessed Single-Use Medical Devices

Health Canada to require all commercially reprocessed single-use medical devices to comply with Canada's *Medical Devices Regulations* by September 1st 2016

Toronto (February 5, 2015) – MEDEC, the national association representing Canada's Medical Technology Companies, expresses its strong support for Health Canada's recent Notice to Stakeholders that it will be holding companies reprocessing single-use medical devices for Canadian healthcare providers to the same regulatory oversight as original equipment manufacturers.

In the Notice issued today, Health Canada announced that companies that reprocess and distribute medical devices originally authorized and labelled for single-use to Canadian healthcare facilities will now be required to "meet requirements for licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents and informing Health Canada of any changes to the information in their licence application." In order to fulfill labelling requirements, the reprocessor will be required to be listed as the manufacturer of the reprocessed device.

The issue is important because medical devices that are licensed by Health Canada to be used only once or on a single patient during a single procedure are currently being reprocessed and reused. In 2008, the Canadian Agency for Drugs and Technologies in Health (CADTH) reported that 28% of hospitals in Canada and 42% of hospitals with over 250 beds were reprocessing single-use devices (SUDs) either in-house or by a third-party reprocessor. In 2015, as a result of provincial policies, third-party companies are now doing the vast majority of reprocessing. Until this recent commitment, companies reprocessing single-use medical devices had not been required to comply with Canada's *Medical Devices Regulations*.

"We are very pleased that the Canadian government is taking the necessary steps to address this long-standing issue and showing its ongoing commitment to patient safety" said Brian Lewis, President and CEO of MEDEC. "Like the United States, requiring companies that reprocess single-use medical devices to comply with the same stringent rules and regulations as original equipment manufacturers is the right thing do."

About MEDEC
MEDEC is the national association representing the medical technology industry in Canada. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our publicly-funded health care system. The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities, and has sales of over $7 billion per annum. We are committed to supporting the growth of a strong and vibrant medical technology industry that contributes to Canada's innovation economy.

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