Dear Speaker Madigan,

Medela LLC (“Medela”), headquartered in McHenry, Illinois, appreciates the opportunity to write to you regarding proposed legislation to restrict or ban the use of ethylene oxide (EO) in Illinois to sterilize critical medical devices.

We respectfully oppose HB 3888 and HB 3885 because their restriction to EO use would lead to the inevitable elimination of EO sterilization in the state and will likely lead to further restrictions in other states. This process is essentially irreplaceable in its effectiveness to combat infection in hospital surgical settings, and is an essential step for Medela to support the most medically fragile in the Neonatal Intensive Care Unit (NICU).

Medela is one of the world’s leading advocates for breast milk with a focus on babies’ health and nutrition. Medela supports babies receiving mothers’ milk early in life by providing research-based products together with clinical education. Every year, over one million mothers in the U.S. rely on our technology. From our McHenry offices, Medela has proudly served hospitals and American families for nearly 40 years, and employs more than 700 full-time personnel across the nation. Our company is fully dedicated to supporting mothers in providing breast milk to their babies for as long as they choose.

The sterilization process that is required for medical device companies is a critically important step to ensure the efficacy of our products for use in the neonatal and hospital environments. We currently sterilize millions of pieces of medical devices at the Medline facility in Waukegan, Illinois and it is our primary sterilizer after the shutdown of Sterigenics earlier this year. While we do have backup suppliers in qualification, the capacity at remaining sterilizers is a major concern for Medela and many other medical device manufacturers dependent on this process.

Medela serves more than 80% of U.S. hospitals and NICUs with sterile breast milk pumping kits, neonatal enteral feeding devices, sterile containers for breast milk and specialty feeding devices used in the NICU. Sterilization is the clinical standard of practice in the NICU to keep dangerous bacteria from appearing and affecting our most vulnerable infants. Ethylene oxide is the recommended sterilization process used on medical devices because many product materials used do not withstand other sterilization methods. It has been reported that failure to comply with sterilization guidelines has contributed to outbreaks associated with contaminated medical devices and surgical instruments.
Before any additional action is taken on EO, the General Assembly needs to recognize the considerable impact such actions would have on hospitals across the country, the care of our most vulnerable populations in the NICU, as well as the Illinois companies that depend upon the use of EO to serve customers nationwide, which includes our most medically fragile infant populations.

Thank you for your attention to our perspectives and concerns. If you have any questions, please either contact me directly or reach out to Michael Torres, General Counsel at 630-885-9414 Michael.Torres@medela.com.

Thank you for your consideration.

Sincerely,

Melissa Gonzales
Executive Vice President of the Americas
Medela LLC
