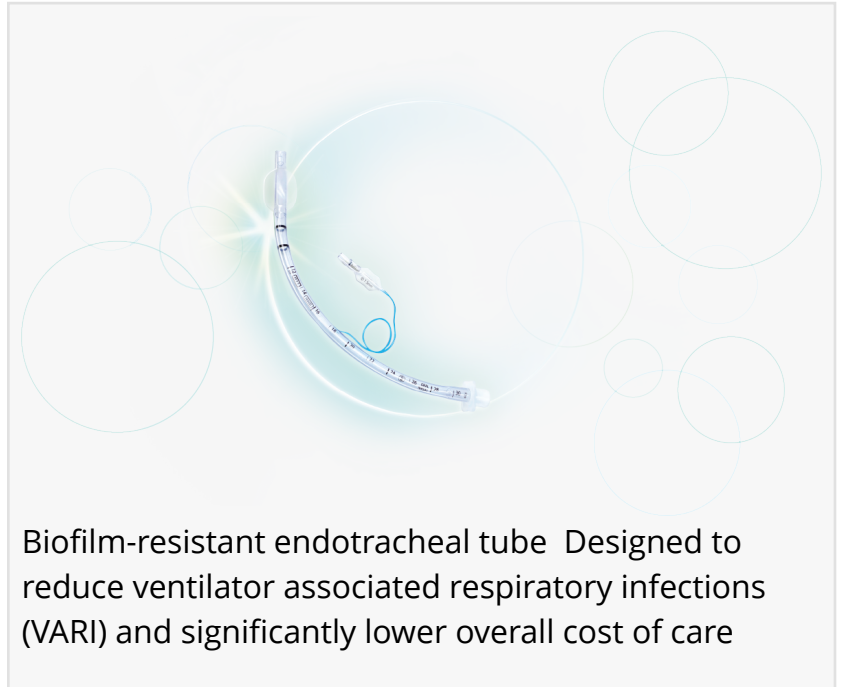


N8 MEDICAL RECEIVES INVIMA APPROVAL TO COMMERCIALIZE ITS CERASHIELD ENDOTRACHEAL TUBE IN COLOMBIA

INVIMA grants N8 Medical authorization for importation and sale of CeraShield ETT for use in adults in intensive care units who require mechanical ventilation.

SALT LAKE CITY, UTAH, UNITED STATES, March 14, 2023 /EINPresswire.com/ -- [N8 Medical](#) ("N8" or the "Company"), a privately held Utah-based biotech company that holds exclusive rights to develop and commercialize a technology platform based on synthetic small molecule compounds ([ceragenins](#)) that mimic the body's own innate immune system, announced today that the Colombia National Food and Drug Surveillance Institute (

[INVIMA](#)), a level four World Health Organization ("WHO") agency, has granted N8 Medical authorization for the importation and sale of its CeraShield™ Endotracheal Tube (ETT) for use in adults in intensive care units who require mechanical ventilation.



Biofilm-resistant endotracheal tube Designed to reduce ventilator associated respiratory infections (VARI) and significantly lower overall cost of care

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We look forward to helping the people of Colombia with our innovative technology that is designed to save lives and reduce the overall cost of care.”

Carl Genburg, N8's co-founder and Chief Development and Scientific Officer

This approval follows those by Health Canada and Brazil's ANVISA. FDA has designated the CeraShield Endotracheal Tube as a “breakthrough device.” N8 Medical plans to initially make its CeraShield ETTs available for evaluation at two of Colombia's leading oncology hospital as cancer patients are at high risk for developing Ventilator Associated Pneumonia (VAP) which is the most common, costly, and deadly of hospital-acquired infections in the Intensive Care Unit (ICU).

Management Commentary

"Colombia has a highly respected health care system and offers universal health care coverage to its citizens," said Carl Genberg, N8's co-founder and



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Chief Development and Scientific Officer. "When the World Health Organization ranked the healthcare systems of 191 countries, Colombia came in at #22. That is better than Canada at #30 and the United States at #37. On top of this, when financial publication América Economía put together their latest annual list of Latin America's top 63 hospitals, 26 of those hospitals were based in Colombia. That means that 41% of the top Latin American hospitals are located in Colombia. Four of these hospitals are Joint Commission International accredited, the gold standard in world health. We look forward to helping the people of Colombia with our innovative technology that is designed to save lives and reduce the overall cost of care." INVIMA has the same level of WHO status as Canada and the United States.

About INVIMA

The Colombia National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos or INVIMA) is a regulatory authority created under the Ministry of Health. INVIMA inspects and supervises the marketing and manufacturing of health products, identifying and evaluating the violation of health standards or procedures, and implementing best practices and providing medical approval for the import and export of products.

About N8 Medical

N8 Medical is a clinical-stage medical device company focused upon commercializing antimicrobial medical devices and coatings to address the multi-billion dollar public health and economic burden associated with medical device-related hospital acquired infections (HAIs). N8 Medical's business is based on the application of a novel, proprietary class of compounds known as ceragenins or CSAs (ceragenins or CSAs) to medical devices for the purpose of transforming existing medical devices into high-value devices with antimicrobial, anti-inflammatory, and other therapeutic properties that improve patient outcomes and lower the overall cost of care. The company's first commercially available device is the CeraShield Endotracheal Tube, designed to prevent potentially lethal infections in critically ill patients who require mechanical ventilation. Other infection prevention applications in development include wound closure devices, vascular access products, and women's health.

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