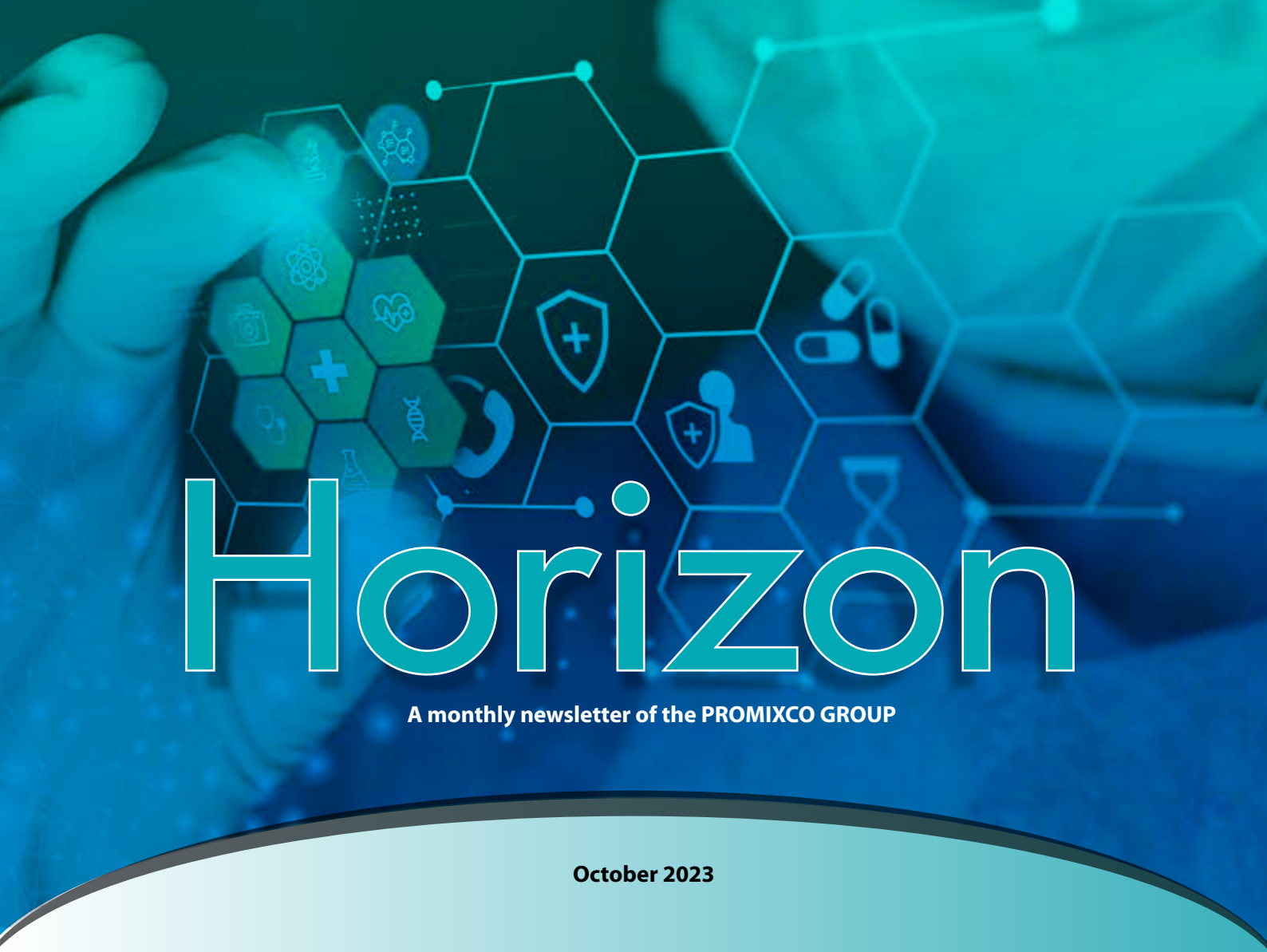

Horizon

A monthly newsletter of the PROMIXCO GROUP

October 2023

MEDICAL DEVICE PRODUCT DEVELOPMENT AND MANUFACTURING

Healthcare Bangladesh News
October 2023

Medical Device Product Development:

We offer a comprehensive suite of services focused on developing and supporting advanced technology solutions. We are experts in complex, efficient devices to increase health services in Bangladesh.

Manufacturing:

Our contract manufacturing capabilities include precision medical extrusion, sub-assembly, and braided tubing for minimally invasive medical devices, as well as full-service silicone component and medical device manufacturing, including long-term implants.
As a single-source provider, we offer unmatched breadth and depth of services to help our customers increase speed to market, reduce risks, simplify supply chains, and ensure accountability. We partner with clients, from small venture-backed firms to the world's largest medical device companies, to find solutions for the most challenging designs, from precision components to completed devices.

Sustainability in Gloves Manufacturing:

In an age where sustainability has become a global imperative, industries increasingly embrace eco-friendly practices. One such industry where sustainability plays a pivotal role is manufacturing personal protective products like gloves. Hand protection is indispensable in various sectors, including construction, healthcare, manufacturing, and more. As we delve into this world, it becomes evident that overall sustainability benefits all stakeholders and businesses.

More transparency is needed in Medical device import:

The Directorate General of Drug Administration (DGDA), a Bangladesh Ministry of Health & Family Welfare division, is the governmental authority responsible for regulating medical device circulation. Bangladesh has taken a significant step forward in enhancing the quality of healthcare services within the country. The Directorate of National Consumer Rights Protection will work to bring "more transparency" in the country's medical device import sector, especially cardiac-related devices.

The move will come in light of a recent drive during which anomalies in selling and managing such medical devices were found; the DG told a meeting at the directorate's office in the capital. "When it comes to this sector, the level of patient satisfaction is deficient," he added. He said that similar medical devices have been sold at two to three times higher prices in Bangladesh compared to a neighboring country. He urged the Directorate General of Drug Administration (DGDA) to enhance its sector inspection.

Registration Validity: The validity of the establishment license is three years, and license renewal shall be applied one year before its expiry date. All manufacturers and AR (foreign manufacturers) must apply for medical device registration; the license is valid for five years.

What Is The Regulatory Classification For Medical Devices?

FDA defines three regulatory controls:

- **Class I :** Medical device (low to moderate risk): General Controls.
- **Class II :** Medical device (moderate to high risk): General and Special Controls.
- **Class III :** Medical device (high risk): General Controls and Premarket Approval (PMA).