



Nymi Band™

The Workplace Wearable Designed
for Cleanroom Use



A new technology paradigm to enhance Good Manufacturing Processes

Leading pharma manufacturers around the world rely on innovation to better serve their customers and maintain a competitive business advantage. Through new technologies, continuous improvement in manufacturing processes is possible, but cannot come with the risk of deviating from governance standards, compliance requirements, or stringent SOPs. Nowhere in pharmaceutical manufacturing are the stakes higher than in cleanroom environments.

Nymi provides a new paradigm for connecting people to their workplace on a platform, which streamlines work securely across different networks and environments. In addition, organizations who deploy the Nymi Connected Worker Platform achieve improved security, data integrity, and agility for implementing future use cases. Employees connect to the platform through one authentication to their Nymi Band and are continuously connected for their entire workday, enabling them to interact with applications in a consistent UX that is passwordless, contactless, and handsfree.

The Nymi Band is a workplace wearable specifically designed for standards governing the highly regulated environments of

pharmaceutical manufacturing industries, and more. In addition, the Nymi Band is designed to minimize risk from contamination, distracted workers, and physical hazards.

Using the Nymi Band in Cleanrooms



Through the Nymi Band's On-Body Detection feature, workers can access physical areas and authenticate to computer systems without touching any equipment. This reduces overall user movement and contact with communal surfaces where transfer of contaminants are more likely to occur. An employee wears and activates their Nymi Band at the start of their shift, before gowning.

The band is designed to be worn comfortably under multiple layers of Personal Protective Equipment (PPE) during the workday, meaning it is never exposed to the cleanroom environment.

Additionally, Nymi Bands that are dedicated to cleanroom use are often stored in a controlled environment, such as a gowning/staging area or employee locker room. Nymi provides reference specifications for the Nymi Band charger to enable our customers to easily design their own bulk storage and charging solutions. Additionally, Nymi will begin offering our own bulk storage and charging solutions starting in 2022.

The Nymi Band: A Design Guided by Industry Input

Nymi works with the top global pharmaceutical, medical device, and nutrition manufacturing companies. We have factored their operational, technical, and quality requirements into the design of the Nymi Band and the [Nymi Connected Worker Platform](#).

Some of the elements designed for cleanrooms include:

- A form factor that minimizes contamination potential and withstands rigorous cleaning protocols
- Functionality that increases automation and operator efficiency, while eliminating potential distractions and unnecessary movement
- Professional services to guide SOP development that comply with an organization's standards

Nymi Bands are currently deployed in the GMP environments of 9 out of the top 10 global pharmas, spanning 16 countries (including the European Union, the United States, Canada, Japan, China, and Singapore). Leveraging insights gained while meeting the rigorous demands in pharmaceutical manufacturing, Nymi is now a leader across critical sectors in terms of function, form, reliability, and employee experience for the most highly regulated industries in the world.

Compliance with Governing Standards

The Nymi Band complies with regulations like those proposed in the 2020 draft of the [European Commission's Annex 1: Manufacture of Sterile Medicinal Products](#), which states in section 7.10¹:

“Wristwatches, make-up, jewellery, other personal items such as mobile phones and any other non-essential items should not be allowed in clean areas. Electronic devices used in cleanrooms, e.g. mobile phones and tablets, that are supplied by the company solely for use in the cleanrooms, may be acceptable if suitably designed to permit cleaning and

disinfection commensurate with the Grade in which they are used. The use and disinfection of such equipment should be included in the CCS.”

The Nymi Band vs Personal Wearables

The Nymi Band is a workplace wearable. Although it looks similar to many consumer wearables, it is distinct in purpose, design, construction, and use. For example:

- The Nymi Band is company property. It can be governed by SOPs that reflect company practices or reinforce compliance with external guidance or regulatory frameworks (e.g., ISO, or Annex 1 for GMP).
- It is typically stored and charged according to company SOPs, often in controlled areas, which present less risk of introducing external contaminants.
- It is designed to be worn under PPE and is never exposed to the environment in a cleanroom.
- It does not display the time nor does it have any non-work-related functions that could distract an operator.

Design & Materials

- The Nymi Band’s materials and finishes are durable, non-porous, and resistant to degradation. As such, there is minimal risk of the Nymi Band itself being a source of contamination.
- The Nymi Band’s materials have been selected and tested to ensure that the Nymi Band can be cleaned frequently to industrial standards.
- The Nymi Band has a smooth surface, low profile, and is worn snug on the wrist under PPE, so there is little risk of physical harm from the device becoming caught or snagged.

For more information about the material composition of the Nymi Band, please visit nyimi.com or ask your Nymi representative.

Daily Use, Cleaning, Charging & Storage

- Customers typically classify the Nymi Band as company-issued industrial equipment, which ensures that it will be governed by SOPs for daily use, cleaning, charging, and storage.
- The Nymi Band is designed for rigorous industrial cleaning with cleaning agents such as isopropanol solution.



For more information about cleaning the Nymi Band, please visit nyimi.com or ask your Nymi representative.

Deployment & Rollout

Prior to a rollout, Nymi will often work with customer personnel to help define or modify SOPs for cleaning, storage, daily use, and other operational aspects of the Nymi Band. Nymi can provide guidance, best practices, and other consulting resources as needed, to ensure optimal performance in the customer's environment.



Please [contact us](#) to learn more about how the Nymi Band and Nymi Connected Worker Platform can bring you greater productivity, a better employee experience, as well as enhanced safety, security, and data integrity – while fully supporting the safety and hygiene of your controlled work environments.



References

- ¹ EU Commission. (2022). [EU GMP Annex 1 Revision: Manufacture of Sterile Medicinal Products \(Draft\)](https://www.gmpcompliance.org/files/guidemgr/2020_annex1ps_sterile_medicinal_products_en.pdf). Retrieve from Section 7.10 https://www.gmpcompliance.org/files/guidemgr/2020_annex1ps_sterile_medicinal_products_en.pdf