

# DRUG DELIVERY COATINGS AND COMBINATION PRODUCTS



 **Hemoteq**

 **FREUDENBERG**  
MEDICAL



## ABOUT HEMOTEQ

**Hemoteq**, a Freudenberg Medical company since 2015, is a leading specialty contract development and manufacturing organization (CDMO) for device drug combination products, medical device coatings & surface modifications.

Our multidisciplinary team's vast experience and IP in surface modification and controlled release formulations provides a solid ground for advanced device coatings and highly innovative combination products.

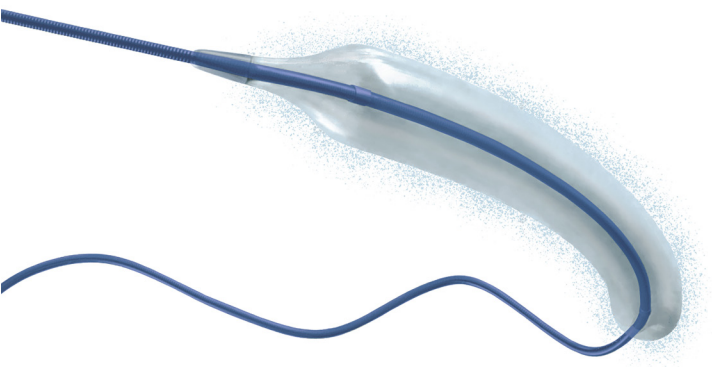
In pursuit of the best possible solutions, we combine the high customization potential of our unique coating platforms with innovative design elements.

Co-creation in dedicated co-development teams is our proven approach to leverage synergies with respect to complementary resource utilization and project acceleration and to achieve outstanding product performance, safety and customer satisfaction.

A modular project structure and individual business entry points ensure high project success rates and short time-to-market. Modules comprise contract design and process development, regulatory approval, contract manufacturing of coated components or final products. By utilizing the growing global resources of Freudenberg Medical, Hemoteq's offering to its customers will progressively expand. Benefit from the unique one-stop-shop offering at Freudenberg, our rapid response capabilities and flexible business models - select the project scope that fits your needs best.

**Demonstrated capabilities:**

- Contract development: drug-eluting stents and drug-coated balloons
- Contract development: wet lubricious coatings
- Contract development: in-house process engineering and equipment construction
- Regulatory approval support for 20+ combination products (CE mark, FDA, NMPA, PMDA)
- Contract manufacturing: scalable in-house serial production of 20+ DES and DCB brands
- Legal manufacturer capabilities for select CE marked combination products



## **FIELDS OF EXCELLENCE**

### **Coating design**

Hemoteq coatings and combination products are uniquely designed to excel in challenging medical applications. We have extensive experience in customizing our coating solutions and drug-excipient formulations to custom device designs, novel device categories and biomaterials that address unmet needs in established or completely new medical applications. In clinical studies and “real world” routine use, our customized coatings proved to impart top performance and safety to drug-coated devices.

### **Coating processes**

Excellence in design and process development lay at the foundations of manufacturability and zero-defect production of all components and devices made by Hemoteq. We employ state-of-the-art manufacturing lines with self-made specialty machinery for spray coating, micro-pipetting and other high-precision coating technologies.

### **Regulatory strategy**

For more than two decades years now, Hemoteq has been co-developing combination products together with renowned global corporations, SME and innovative start-ups. Working with recognized European notified bodies and competent authorities, Hemoteq has yielded an impressive track record of successful CE marking for combination products and Class III devices. We implement our expertise in regulatory strategy in any and every project, thereby optimizing prospects of success and time-to-market.

### **Contract manufacturing**

As a versatile medical technology manufacturer we provide specialty CMO capabilities for device coatings of variable complexity. Spacious high-tech Class 7 cleanrooms, self-made special coating equipment and high-throughput production lines enable us to process all your orders efficiently, with consistently high quality. Our CMO services range from prototypes and pilot lots to scalable serial production. Hemoteq is EN ISO 13485:2016 and ISO 14001:2015 certified.

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