

# Life science



## World-class quality management

Pharma + Medico + HealthTech + BioTech

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**D4**InfoNet®

# HEKA

## Digitised workflows from start to finish

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**D4InfoNet is an integral part of the quality management of Heka Dental A/S, which manufactures dental chairs for customers all over the world. *"We received a good offer for a standard solution that was just right for us, and both implementation and validation went quickly and smoothly,"* says quality manager Claus van der Goot. He explains how the system matches Heka Dental's everyday life and reality.**

"Previously, all our documentation was Word documents that had to be signed every time something was changed – which was often. It was a huge job to keep track of and, therefore, we decided to find a digital solution that could meet our needs for both document management and validation."

"Today, all the processes and technical files for every unit we produce are gathered in manuals on D4InfoNet. This is where we also have our quality management, quality meetings and chairpersons' meetings. Everything is digital and in one place, making the approval processes for changes or updates much easier than if they were in paper form."

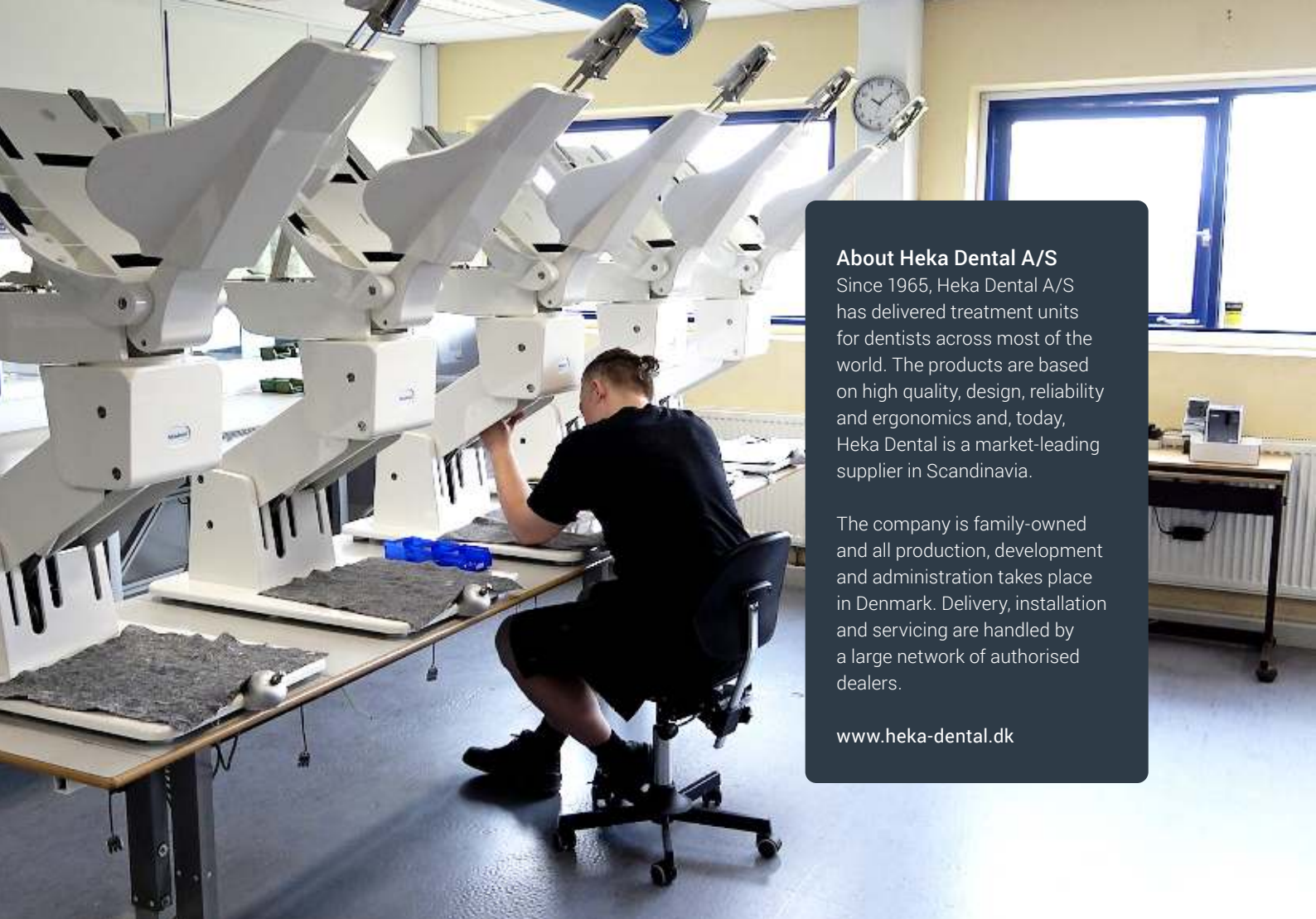
### **Streamlined Change Orders**

"For example, we have developed a workflow that streamlines our process for Change Orders. If a salesperson, technician or other employee has a good

idea – or if events occur (CAPAs) that require regulatory changes – you go in and create a Change Order in D4InfoNet. Here you describe your proposal and can add pictures or sketches, for example."

"After that, Change Order is automatically sent to me. I assess the regulatory influence, whether the changes are in accordance with ISO 13485 and applicable regulations, and whether there is a need to change our technical files. For security-related incidents, I also look at whether it should be reported to the authorities and Notified Body. Then our director assesses the commercial consequences and finally we communicate the change to the relevant departments."

"Previously, the process consisted of a pile of papers wandering between people, but now it's digitised from start to finish in D4InfoNet with a workflow built from standard forms adapted to our wishes."



### About Heka Dental A/S

Since 1965, Heka Dental A/S has delivered treatment units for dentists across most of the world. The products are based on high quality, design, reliability and ergonomics and, today, Heka Dental is a market-leading supplier in Scandinavia.

The company is family-owned and all production, development and administration takes place in Denmark. Delivery, installation and servicing are handled by a large network of authorised dealers.

[www.heka-dental.dk](http://www.heka-dental.dk)

### Overview of suppliers, equipment and events

"Today we also use D4InfoNet for supplier assessment, equipment calibration and event registration. For example, all of our equipment must be calibrated at regular intervals, and we control this using a form in D4InfoNet. The system sends a notification in advance, and you can attach certificates and other relevant material to the equipment. It's really convenient."

### Digital processes for audits, HR and risk analysis

"In addition, we use the system for auditing – we have just adapted the module to match ISO 13485 and

applicable regulations – and we also have the HR module so that we can document that our employees are qualified for the tasks they perform."

"We have recently started implementing D4InfoNet's module for risk analysis. We have 400 defined risks, which are currently in one of the aforementioned Word documents. These have been converted in cooperation with D4 so that they are all in separate analyses. This makes our risk analysis much clearer and a more integrated part of our quality processes."



**"We ended up choosing D4InfoNet because it is simple and user-friendly, and because the system can be validated, which is a requirement for the software we use."**

**Claus van der Goot**  
Quality Manager (PRRC)

### **Safe storage of documentation**

"It is easy and simple for us to live up to the requirements associated with archiving and storage. We have an expiry period of 10 years, i.e. we must retain the documentation on a product for 10 years after the product has been discontinued and taken out of production."

"According to EN/ISO 13485, you mustn't have documents lying around that could be damaged by water or fire, for example. This was the original reason why we acquired the system in 2018 and began to enter all the documentation. Now, two years later, we've almost gone through the 20 shelves of binders we had when we started."

### **D4 has experience with the industry**

"When we searched the market, we looked at a couple of American systems, among others, but they were too expensive and with the time difference for support, it would just be too inconvenient."

"We ended up choosing D4InfoNet because it is simple and user-friendly, and because the system can be

validated, which is a requirement for the software we use. We received a good offer for a standard solution that was just right for us, and both implementation and validation have gone quickly and smoothly. It also means a great deal that D4 has experience with our industry."

### **Everyone at Heka Dental cares about quality**

"D4InfoNet gives you a much better overview of the processes, and you don't forget or miss a task or action because the system automatically reminds you of them."

"On the other hand, it can take some time for employees to get used to letting go of the paperwork, and as a quality manager it requires resources to ensure that everyone receives training and knows how to use the system, but I think the transition has gone well."

Everyone in our company is self-respecting and cares about quality, and today the paper has almost disappeared. People have realised that it is easier and more transparent this way."



D4 ApS provides flexible software solutions that meet specific needs within organisational process optimisation.

We serve a large number of public and private customers within life science, the food industry, health, research, the environment, IT and manufacturing.

We serve both small businesses with few employees, medium-sized organisations with many departments and multinational companies with thousands of employees.

We are certified according to ISO 9001 and ISO 27001.

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