MDR from a small company's perspective

To stay in MDD or early transition to MDR

– Zenicors perspective and strategy.

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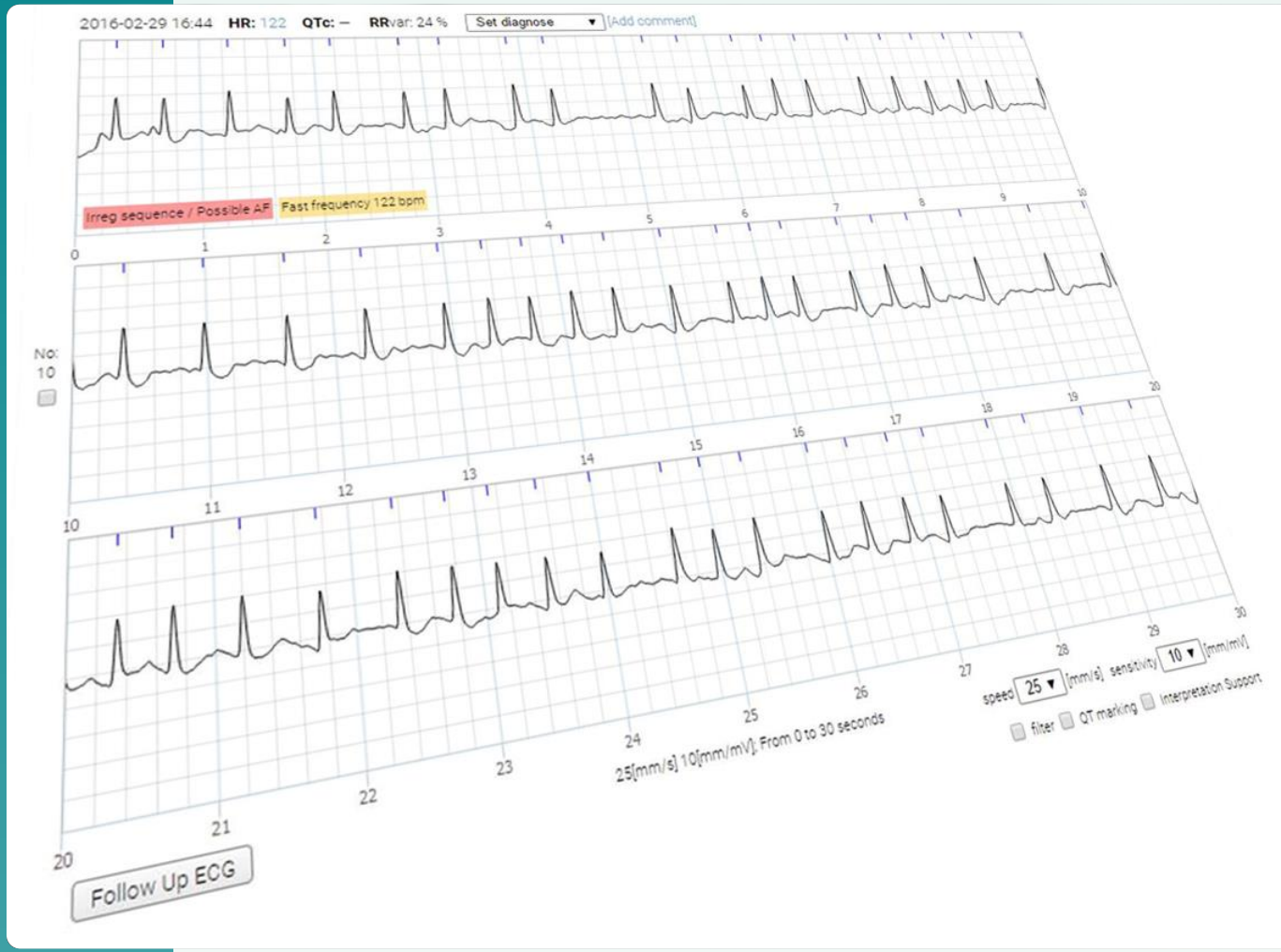
Regulatory summit 2018

Zenicor Medical Systems AB

- Founded: 2003 (in Stockholm)
- Turnover: 21 million SEK
- 18 employees (12 within Sales & Marketing)
- Zenicor EKG-2 device, MDD class IIa (since 2010)
- Zenicor-EKG Back-end system, MDD class IIa (since 2004)



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Gustav Lins

- Operations and Quality Manager at Zenicor
- Responsible for the Quality and Regulatory Affairs
- More than 10 years of experiance from the Medtech industry both from small and large companies
- Global resposibility for Quality and Regulatory Affairs at Sectra, Philips, Swemac Imaging and Demetech.
- Gustav loves Medtech products

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Major business risks associated choosing the road MDR "direct"

- Notified Body ready for MDR?
- Resources needed to create all MDR documentation?

Zenicor's MDD/MDR journey

2017

- ISO & MDD audit
- Unannounced visit by NB

2018

- ISO & MDD audit
- Update CER according to MEDDEV 2.7/1 rev 4
- TF review Back-end system
- Also GDPR

2019

- Re-certification audit ISO13485:2016
- TF review EKG-2
- New EC cert

2020

- ISO & MDD audit
- Update QMS due to MDR requirements

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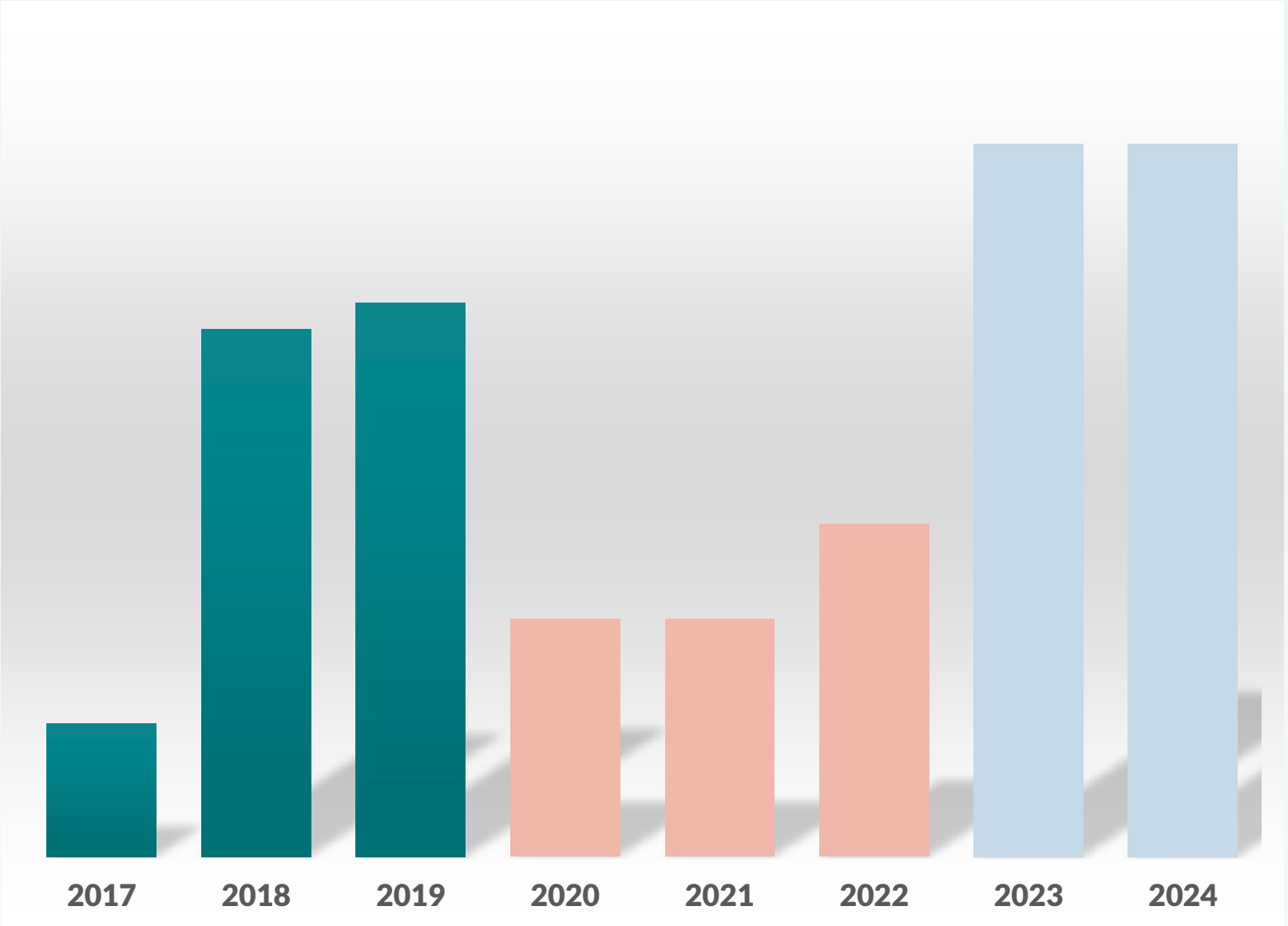
Costs



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Next step towards MDR for Zenicor

- Zenicor needs to transfer products to MDR before 2024.
- Limitations with regards to design changes since the products will remain within MDD.

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Looking ahead

- Patient safety and clinical benifits will always be the main objective within the Medtech industry.
- Will Medtech products be safer within MDR than MDD?
- Will we create more patient benefits within MDR than MDD?
- Should we except that regulatory submissions to CA and NB will become longer, more expensive and less predictable?
- Will more small companies ”disappear” into the large ”Dragons”?
- Will there be more obstacles for a small company to enter the Medtech industry due to MDR?

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