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**SOUTH AFRICA –  
LOCALISATION AND  
REGULATION**  
Impact on the Market

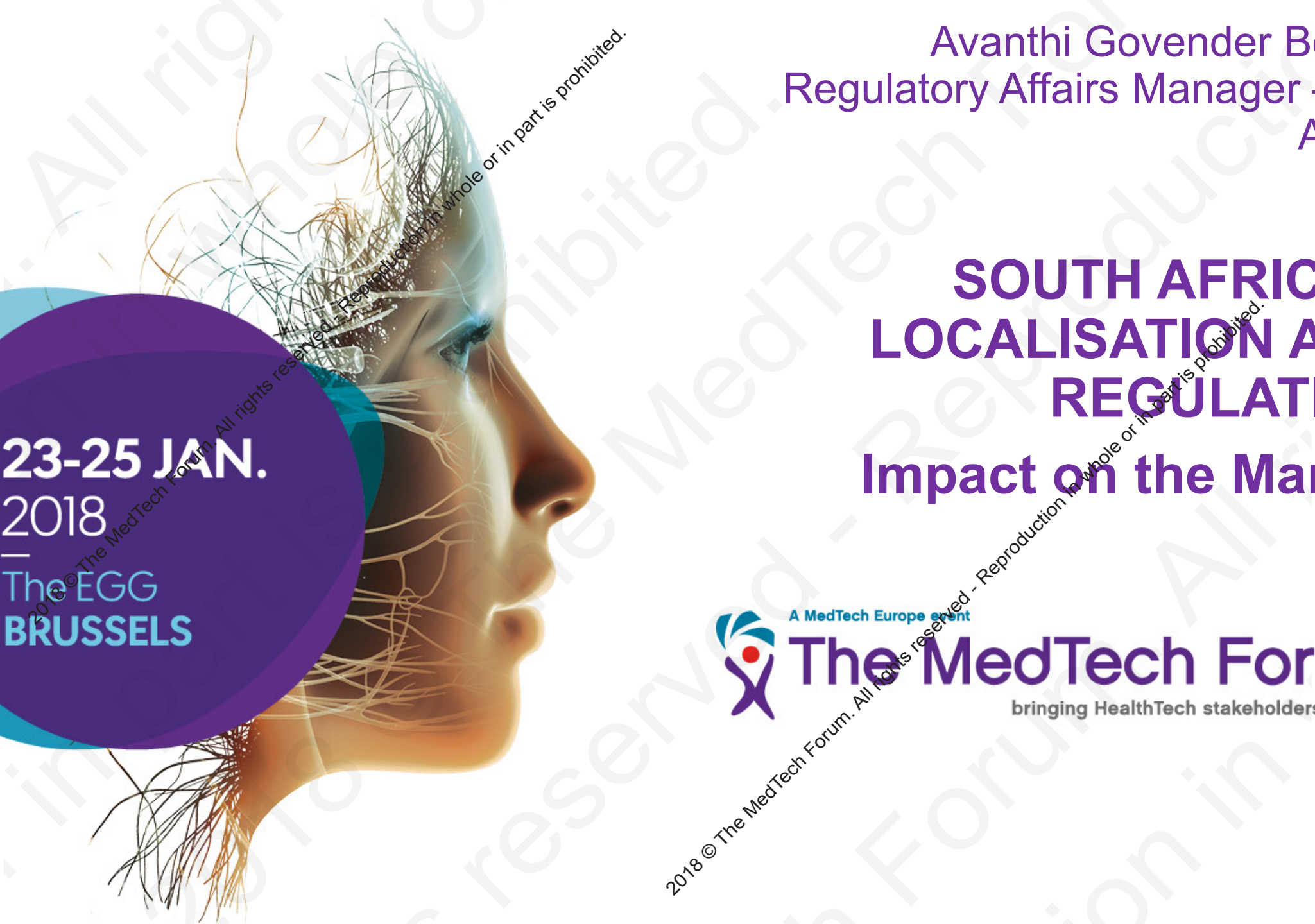
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The EGG  
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# A COMPANY PERSPECTIVE

- Establishment Licensing
- Listing of Products for Sale in SA
- Localisation of products

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# ESTABLISHMENT LICENSING

1. Definition of a manufacturer, distributor and wholesaler
2. Appointment of the Authorised Representative
3. Quality Management System
4. Fees
5. Contracts and Quality Agreements

# LISTING OF PRODUCTS FOR SALE

1. IVD and non-IVD products
2. Classification
3. GMDN code
4. Veterinary Products
5. Recognition countries
6. High-risk product requirements

# LOCALISATION

## Tenders/Supply of products to the Government

- Local secondary packaging
- Local labeling
- Local over-labelling
- Local kitting