Bundesverband der
implantologisch
tätigen Zahnärzte
in Europa

European
Association of
Dental
Implantologists

European Medical Device Regulation MDR

Post-market Surveillance (PMS) – Vigilance System

Name of owner of the dental/practice lab

To be monitored:

-- Complaints and goodwill
-- Manufacturer's response relating to material
-- Patients' complaints officially recorded by relevant competent authority

Relevant product groups:

Dentures and therapeutic appliances within the following sub groups

- ❑ fixed prosthesis
- ❑ CAD/CAM
- ❑ removable prosthesis
- ❑ splints
- ❑ orthodontics
- ❑ extensions fabricated in the dental/practice lab
- ❑ restorations fabricated in the dental/practice lab

Review will be done:

❑ within the 2-year-routine inspection

or

❑ incident-related

Define incident (e.g. complaints, feedback from the manufacturer etc.)

_____

_____

Responsible person for compliance of this programme according to article 15 MDR

_____

Full name of person responsible

Evaluation of the monitoring measures

Annual period _____

Total number of complaints within this period _____

Information considered from relevant competent authority _____

Feedback considered from manufacturer _____

Serious material-related incidents _____

The following action options result from above evaluation

– Does a new hazardous situation arise? ❑ yes ❑ no

– Is a replacement of selected devices necessary? ❑ yes ❑ no

– Is a recall of devices necessary? ❑ yes ❑ no

– Are there any notifiable incidents? ❑ yes ❑ no

– Is the recorded data sufficient? ❑ yes ❑ no

– Is there a change of risk analysis necessary? ❑ yes ❑ no

Conclusion

– Is the risk assessment sufficient? ❑ yes ❑ no

– Have the specified measures been implemented? ❑ yes ❑ no

– Is the benefit greater than the risk? ❑ yes ❑ no

_____ _____

Issued on *Issued by*

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