

# DataRiver

## MEDICAL DEVICE MANUFACTURER

DataRiver Quality System implements Standard Operating Procedures to document and manage the design and development of stand-alone software classified as medical devices, certifying the compliance of hardware and software platforms and of processes with:

- ▶ EN ISO 13485 Medical Devices - Quality management systems
- ▶ Reg. (EU) 2017/745 Regulation on medical devices

## ARIA VIDEO VISIT

The ARIA platform has a telehealth module that allows medical staff to:

- ▶ interact remotely with patients,
- ▶ manage a calendar with scheduled video visits with them, and
- ▶ schedule a new follow-up.



## PHYSIOLOGICAL PARAMETERS

- ▶ QT, PR and QRS based on ECG
- ▶ Atrial fibrillation based on PPG
- ▶ Average, Minimum, Maximum HR
- ▶ Apnea-Hypopnea Index
- ▶ SPO2 Oxygen saturation

## ePRO QUESTIONNAIRES

- |             |          |
|-------------|----------|
| ▶ EQ-5D-5L  | ▶ PAOFI  |
| ▶ HeartQoL  | ▶ FAS    |
| ▶ IPAQ-SF   | ▶ GHQ-12 |
| ▶ KCCQ -12  | ▶ PHQ-2  |
| ▶ EXACT     | ▶ GDS    |
| ▶ DAAS-21   | ▶ GSRS   |
| ▶ STOP-Bang | ▶ PSQI   |
| ▶ MRC DS    | ▶ MLHFQ  |
| ▶ ESS       | ▶ SF-12  |
|             | ▶ ISI    |



## TELEMEDICINE PLATFORM

### MDR Class IIa

ARIA is a Telemedicine Platform certified as Class IIa medical device, designed to ensure effective interaction between healthcare professionals and patients, offering new ways to remotely monitor patients' health and quality of life.

DataRiver

CE 1936  
Medically Certified



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MAKING  
HEALTHCARE  
ACCESSIBLE



## UNIFIED DISPLAY AND EVALUATION OF INFORMATION

ARIA offers a unified display and evaluation of information obtained from:

- ▶ patient-completed questionnaires (ePRO) via smartphones and tablet
- ▶ data and physiological parameters (vital and non-vital) collected from medical devices



The ARIA platform provides:

- ▶ a telemonitoring system using medical devices to monitor patients on physiological parameters and collect their data on physical activity
- ▶ a Video Visit system that allows medical staff to interact remotely with the patient
- ▶ a Voice Assistant to improve communication and support between medical staff and the patient

## ARIA REAL-TIME MONITORING

Through specific customizable graphs on the ARIA dashboard, medical staff can remotely monitor trends in vital and non-vital parameters, collected from medical devices used by patients. Medical staff can set pre-alert thresholds on specific patient's physiological data and will be notified when these thresholds are exceeded.

## UNDERSTANDING PATIENT'S HEALTH PATIENT REPORTED OUTCOMES

ARIA processes ePRO questionnaire scores, therefore enabling medical staff to understand the patient's health status. Medical staff may receive a text message when a patient-specific threshold is exceeded



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